IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
	)	
EXACTECH, INC., *et al.*[1]	)	Case No. 24-12441 (LSS)
	)	
Debtors.	)	(Jointly Administered)

UNITED STATES OF AMERICA, ex rel., BROOKS WALLACE, ROBERT FARLEY and MANUEL FUENTES	)	
Plaintiffs,	)	
v.	)	Adv. Pro. 25-_____
EXACTECH, Inc.,	)	
Defendant.	)	

COMPLAINT TO DETERMINE DISCHARGEABILITY

Relators Brooks Wallace, Robert Farley, and Manuel Fuentes, on behalf of themselves, the United States of America, ex rel. (collectively, the "Plaintiffs"), allege and claim against Exactech, Inc., as follows:

BRIEF STATEMENT OF THE CASE

1. This is an adversary proceeding to determine the dischargeability of debts arising pursuant to certain *qui tam* causes of action against Defendant Exactech, Inc. ("Defendant" or

[1] The Debtors in these jointly administered cases are Osteon Holdings, Inc.; Osteon Intermediate Holdings I, Inc.; Osteon Intermediate Holdings II, Inc.; Exactech, Inc.; and XpandOrtho, Inc.

"Exactech") based on fraud and on violations of the False Claims Act (31 U.S.C. §§ 3729 *et seq.*), litigation on which is currently pending in the United States District Court for the Northern District of Alabama, case number 2:18-cv-01010-LSC. Exactech violated the False Claims Act by submitting, and causing the submission of, false claims for payment to government health care programs including Medicare, Medicaid, Veterans Administration, and Tricare programs by selling a known defective and misbranded medical device—the Optetrak Total Knee Replacement ("TKR") with Finned Tibia Tray—for use in the care of government-insured patients, when this device was known by Exactech to be defective and not reasonable and necessary for treatment, in violation of 42 U.S.C. § 1395(a)(1)(A), and misbranded, in violation of 21 U.S.C § 352. In furtherance of a conspiracy to submit false claims and to conceal and avoid repayment of obligations to repay the Government, Exactech concealed the device's defects and failures. Exactech offered and provided illegal remuneration in order to prevent the disclosure of device failures and to induce orthopedic surgeons to continue to use its products, in violation of 42 U.S.C. § 1320a-7b. Exactech's scheme callously caused severe patient harm to veterans, the elderly, and the poor, all to profit from taxpayers and avoid business losses.

JURISDICTION AND VENUE

2. This action arises under 11 U.S.C. § 1141(d)(6)(A), which incorporates 11 U.S.C. § 523(a)(2) and causes of action falling under Subchapter III of Chapter 37 of Title 31, including the False Claims Act, 31 U.S.C. §§ 3729-33. Therefore, this Court has jurisdiction pursuant to 28 U.S.C. § 1334 and the District Court's standing order referring all bankruptcy matters to this Court.

3. This is a core proceeding pursuant to 28 U.S.C. § 157(b)(2)(I). To the extent that this Court would otherwise lack authority to enter a final order, the Plaintiffs consent to final adjudication by this Court.

4. Venue lies in this judicial district pursuant to 28 U.S.C. § 1409.

PARTIES

5. Relator Manuel Fuentes, MD, is an orthopedically trained physician with over twenty years of experience in the orthopedic device industry who was employed by Defendant Exactech from 2006 to 2011. Dr. Fuentes has personal knowledge of failures of the Finned Tibia Tray Optetrak TKR, Exactech's corporate knowledge of those failures, and Exactech's cover-up scheme.

6. Relator Brooks Wallace was an Exactech sales representative from 2011 to 2013 and co-owner and managing partner of Gulf Surgical Solutions, an Exactech distributorship covering Alabama and the Florida Panhandle, from 2013 to January 2017. Relator Wallace has personal knowledge of Exactech's false advertising and sale of the defective and misbranded Finned Tibia Tray Optetrak TKR and Exactech's attempt to conceal device failures through denial, cover-up, and illegal remuneration to induce further use of Exactech products.

7. Relator Robert Farley was an Exactech sales representative in 2012 and co-owner of Gulf Surgical Solutions from 2013 to January 2017. Relator Farley has knowledge that the Finned Tibia Tray Optetrak TKR failures were widespread and that multiple other Distributors reported failures to Exactech's leadership as early as 2007.

8. Defendant Exactech, Inc. is a manufacturer of orthopedic implant devices and related surgical instrumentation based in Gainesville, Florida.

9. Prior to filing this Complaint, Relators voluntarily disclosed to the United States the information described herein. To the extent that any public disclosure has taken place as defined by 31 U.S.C. § 3729(e)(4)(A), Relators are the original source of the information for

purposes of that section. Alternatively, Relators have knowledge that is independent of and materially adds to any purported publicly disclosed allegations or transactions.

APPLICABLE LAW

A. Corporate Debtor Non-Dischargeability

10. The Bankruptcy Code excepts from discharge by a corporate debtor any debt "of a kind specified in paragraph (2)(A) or (2)(B) of section 523(a) that is owed to a domestic governmental unit, or owed to a person as the result of an action filed under subchapter III of chapter 37 of title 31 or any similar State statute[.]" 11 U.S.C. § 1141(d)(6)(A). This subsection "is properly analyzed as providing two separate and independent discharge exceptions, and the limiting phrase 'of a kind specified in *paragraph (2)(A) or (2)(B) of section 523(a)*' modifies only any debt 'that is owed to a domestic governmental unit,' and does not modify any debt 'owed to a person as a result of an action filed under subchapter III of chapter 37 of title 31 or any similar state statute.'" *United States ex rel. Minge v. Hawker Beechcraft Corp. (In re Hawker Beechcraft, Inc.)*, 515 B.R. 416, 425 (S.D.N.Y. 2014) (italics in original).

B. Exceptions to Discharge, Including Claims Based Upon Fraud

11. The Bankruptcy Code excepts from discharge any debt "for money, property, services, or an extension, renewal, or refinancing of credit, to the extent obtained by –

> (A) false pretenses, a false representation, or actual fraud, other than a statement respecting the debtor's or an insider's financial condition; [or]
>
> (B) Use of a statement in writing –
> (i) that is materially false;
> (ii) respecting the debtor's or an insider's financial condition;
> (iii) on which the creditor to whom the debtor is liable for such money, property, services, or credit reasonably relied; and
> (iv) that the debtor caused to be made or published with intent to deceive[.]"

11 U.S.C. § 523(a)(2)(A)-(B).

12. A party asserting non-dischargeability under 11 U.S.C. § 523(a)(2)(A) must prove that:

a. the debtor made the misrepresentations or perpetrated fraud;

b. the debtor knew at the time that the representations were false;

c. the debtor made the misrepresentations with the intention and purpose of deceiving the creditor;

d. the creditor justifiably relied on such misrepresentations; and

e. the creditor sustained loss and damages as a proximate result of the misrepresentations having been made.

Webber v. Giarratano (In re Giarratano), 299 B.R. 328, 334 (Bankr. D. Del. 2003).

C. The Federal False Claims Act & Anti-Kickback Statute

13. The False Claims Act (or "FCA") provides, *inter alia*: any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (3) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government or (4) conspires to commit a violation of the False Claims Act is liable to the United States for a civil monetary penalty of not less than $5,500 and not more than $11,000, plus treble damages. 31 U.S.C. § 3729(a)(1)(A), (B), (C), (G). A claim that includes items or services resulting from a violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), constitutes a false or fraudulent claim under the FCA.

D. Government Health Care Programs

1. The Medicare Program

14. Medicare Hospital Insurance Benefits for the Aged and Disabled – commonly referred to as "Medicare Part A" – entitles beneficiaries to in-patient hospital services and post-hospital extended care services. 42 U.S.C. § 1395d. The costs of TKR surgery related to the in-patient care including the cost of the implant device and a patients' in-patient hospital stay are covered under the provisions of Medicare Part A. *Id.* The costs of a TKR surgery related to the cost of the device and inpatient care are billed by a hospital under Medicare Part A as part of a Diagnosis Related Group ("DRG") payment. *See* 42 C.F.R. § 412.60.

15. Hospitals submit claims for inpatient care and medical devices under Medicare Part A using an institutional claim format known as the ASC X12 837, or where permissible, the hardcopy version Form CMS-1450. ASC X12 837 I and Form CMS-1450 are processed and paid for by the Medicare Administrative Contractor responsible for processing and paying the hospital's claims. *See* Medicare Claims Processing Manual Ch. 3 § 10.1. Submission of a ASC X12 837 I or Form CMS-1450 when permissible requires the following certification:

> "Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete. That the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts."

16. At the end of the fiscal year, CMS requires hospitals to file an annual "cost report," which is CMS Form 2552. The hospital cost report is the final claim a provider submits to a MAC for items and services rendered to Medicare beneficiaries during that fiscal year. Included in the hospital cost report is the stated amount of Medicare Part A reimbursement the hospital believes is due for the year or the amount of excess reimbursement the hospital received from interim payments which the hospital must refund to Medicare. *See* 42 U.S.C. § 1395(g)(a); 42 C.F.R.

§ 413.24. Medicare relies on the hospital cost report to determine whether the provider is entitled to more reimbursement than it has received through interim payments or whether the provider has been overpaid and must refund Medicare a portion of the interim payments. 42 C.F.R §§ 405.1803; 413.60.

17. When submitting a hospital cost report, a provider must also submit a hard copy of a "settlement summary," which is a statement of certain worksheet totals – related to the payment for services requested and a "certification statement." 42 C.F.R. § 413(f)(4)(iv).

18. The certification statement required to be signed by the hospital's administrator or chief financial officer and submitted with the cost report, includes the following section:

> MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

42 C.F.R. § 413.24(f)(4)(iv); FORM CMS-2552-10.

19. The "certification statement" also requires the hospital's administrator or chief financial officer to certify:

> I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.

FORM CMS-2552-10.

20. Therefore, each hospital cost report must provide an express, material, certification that the services and claims submitted in the report were billed in compliance with applicable laws and regulations, including the AKS.

21. Medicare Part B covers services and supplies furnished by physicians or others in

connection with physicians' services, outpatient hospital services, outpatient physical therapy and occupational therapy services, home health services, purchase or rental of durable medical equipment, ambulance services, prosthetic devices, and certain medical supplies. 54 Fed. Reg. 4302, 4303–04 (Jan. 30, 1989). Included in these payments are the outpatient and physical therapy portions of a patient's care related to TKR surgery. 42 U.S.C. § 1395k.

22. Healthcare providers submit claims covered by Medicare Part B by submitting the ASC X12 837 professional claim format or, where permissible, Form CMS 1500. Medicare Claims Processing Manual Ch. 3 § 10.1.

23. Form CMS 1500 includes this Certification and Notice provision:

> This is to certify that the foregoing information is true, accurate and complete…this claim whether submitted by me or on behalf of my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute...services on this form were medically necessary…I certify that the services listed above were medically indicated and necessary to the health of this patient… I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents or concealment of a material fact may be prosecuted under applicable Federal or State laws.

24. Each Medicare Part B billing related to physician's services, rehabilitation services, or other outpatient care attendant to a knee replacement surgery must provide an express material certification that the services and claims submitted in the annual cost report were billed in compliance with applicable laws and regulations, including the AKS and 42 U.S.C. § 1395y(a)(1)(A).

25. To bill Medicare for professional claims, the physician or entity must complete a Medicare Enrollment Application, Form CMS-855I, containing a "certification statement and signature" that requires the physician to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in section 4A of this application. The

> Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social Security Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (section 1877 of the Social Security Act)).

and

> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

26. It is a universal requirement of the Medicare program that all items and services provided to beneficiaries must be reasonable and medically necessary. *See* 42 U.S.C. § 1395y(a)(1)(A). It is axiomatic that the government controls Medicare costs by denying coverage claims for items or services that are not "reasonable and necessary" for treatment.[2] A device is not "reasonable and necessary" and thus is not eligible for Medicare coverage if it is not "safe" and "effective" – that is, if the device has not been proven safe and effective based on authoritative evidence or is not generally accepted in the medical community as safe and effective for the condition for which it is used.[3]

2. The Federal/State Medicaid Programs

27. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments varies by state and is generally between 50 and 83 percent, depending on the state's per capita income. 42 U.S.C. § 1396d(b). Most states' definition of medical necessity mirrors that of the Federal Medicare definition. *See, e.g.*, Florida Administrative Code (Rule 59G-1.010).

[2] *International Rehabilitative Sciences Inc. v. Sebelius*, 688 F.3d 994, 997 (9th Cir. 2012) citing 42 U.S.C. § 1395y(a)(1)(A).
[3] *Id.*; 54 Fed.Reg. 4302, 4303–04 (Jan. 30, 1989).

3. The Veterans Administration

28. The Veterans Administration ("VA") maintains a system of medical facilities that provide Veterans with medical care, including TKR surgeries. The VA operates by purchasing medical supplies such as knee replacement implants directly from device manufacturers through the Federal Supply Schedule ("FSS"). Medical equipment and supplies contracts, such as knee replacement devices, are governed by the FSS Group 65, Part II, Section A.

E. Government Regulation of Medical Devices

29. The Medical Device Amendments of 1976, 21 U.S.C. §§ 360c *et seq.*, amended the Food Drug and Cosmetic Act ("FDCA") to "provide for the safety and effectiveness of medical devices intended for human uses." Pub. L. No. 94-295, 9 Stat. 539, 53 (May 28, 1976) (preamble).

30. The Medical Device Amendments established three classes of medical devices: Class I, Class II, and Class III. 21 U.S.C. § 360c.

31. As a "knee joint patellofemorotibial polymer/metal/polymer semi – constrained cemented prosthesis intended to replace a knee joint," the Exactech Optetrak TKR is classified as a Class II device. *See* 21 C.F.R. § 888.3560. As a Class II device, Exactech was required to obtain approval from the Food and Drug Administration ("FDA") to market the Optetrak TKR with the Finned Tibia Tray via the 510(k) process. To obtain approval under the 510(k) process, a device manufacturer needs to show that the device is "substantially equivalent" to a device that has been previously approved by the FDA. *See* 21 C.F.R. § 807.92. However, 510(k) process does not require clinical data showing safety and effectiveness for the device being assessed.

32. Exactech obtained 510(k) approval of the Optetrak with Finned Tibia Tray on October 20, 1994.

33. The Medical Device Amendments denote Class II devices as requiring "special

controls" because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device. These special controls focus on the obligations of device manufacturers and importers to report problems with its marketed devices to the FDA.

34. One area of post-market surveillance special controls is the Medical Device Reporting ("MDR") requirements, defined in 21 C.F.R. § 803, as authorized by Section 519 of the FDCA. The MDR regulation provides a mechanism for the FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals are to detect and correct problems in a timely manner. The FDA relies on the goodwill and cooperation of all affected groups to accomplish the objectives of the regulation.[4]

1. Device Misbranding: Statutes and Regulations That Were Violated

35. "A device shall be misbranded if its labeling is false or misleading in any particular." 21 U.S.C. § 352(a)(1). "The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). "If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the

[4] Medical Device Reporting for Manufacturers. Guidance for Industry and Food and Drug Administration Staff. U.S. Department of Health and Human Services. Food and Drug Administration, Center for Device and Radiological Health. March 1997. Available at https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB99105421.xhtml

labeling or advertising thereof or under such conditions of use as are customary or usual." 21 U.S.C. § 321(n).

36. "A device shall be misbranded…if there was a failure or refusal to furnish any material or information required by or under section 360i [FDA adverse event reporting requirements]." 21 U.S.C. § 352(t).

37. A device that is "misbranded" may not be sold in the United States and therefore may not be sold to government health care programs such as Medicare, Medicaid, TRICARE, and the VA. 21 U.S.C. § 331.

2. Current Good Manufacturing Practices Requirements That Were Violated

38. Medical device manufacturers must adhere to "Current Good Manufacturing Practices" ("cGMP")—which contain the minimum requirements that device manufacturers must meet to "assure that the device will be safe and effective." 21 U.S.C. § 360j(f). Devices not manufactured in accordance with cGMP standards are considered "adulterated" and may not be marketed in the U.S. nor sold to federal health insurance programs. 21 U.S.C. § 331.

39. As part of the required cGMP, device manufacturers must develop, conduct, control, and monitor production to ensure that devices conform to their specifications. Where deviations from specifications could occur due to the manufacturing process, the manufacturer must establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. 21 C.F.R. § 820.70.

40. Manufacturing process controls must include documented instructions, standard operating procedures, and methods that define and control the manner of production. The manufacturer must also develop production and process controls, establish and maintain procedures for changes to a specification, method, process, or procedure, such changes must be

validated before implementation, and such validation activities must be documented. 21 C.F.R. § 820.70

3. Mandatory Reporting Requirements That Were Violated

41. A device manufacturer must submit initial and supplemental reports to the FDA no later than 30 calendar days after the day that the manufacturer "receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device that [the manufacturer] market(s): (A) may have caused or contributed to a death or serious injury, or (B) has malfunctioned and that such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 C.F.R. § 803.50; 21 U.S.C. § 360i.

42. "Devices may cause or contribute to MDR reportable events either directly or indirectly." 60 Fed. Reg. 63578, 63585 (Dec. 11, 1995); 21 C.F.R. § 803.3(c) (a device has "caused or contributed to a reportable death or serious injury if the device was or may have been a factor in a death or serious injury").

43. When a manufacturer learns of an adverse (or "reportable") event, such as a Total Knee Replacement Revision surgery, the manufacturer must submit the following information: (i) any information that the manufacturer can obtain by contacting a user facility, importer or other initial reporter; (ii) any information in the manufacturer's possession; and (iii) any information that the manufacturer can obtain by analysis, testing, or other evaluation of the device. 21 C.F.R. § 803.50(b)(1). The manufacturer is responsible for conducting an investigation of each event and evaluating the cause of the event. 21 C.F.R. § 803.50(b)(3).

44. These reporting requirements are ongoing; if a manufacturer later obtains information that was not available at the time the manufacturer filed its' initial, the manufacturer must supplement. 21 C.F.R. § 803.50(b)(3).

45. The MDR Requirements have developed Form FDA 3500A, which provides the discrete categories of information required to be submitted with an individual adverse event report. 21 C.F.R. § 803.52. If a Form 3500A report omits any required information, the manufacturer must explain why this information was not provided and the steps taken to obtain this information. *Id.*

4. Remedial Action

46. Device manufacturers must submit a report within 5 workdays after the day that the manufacturer becomes aware that an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. 21 C.F.R. § 803.53. This requirement emphasizes that a manufacturer "may become aware of the need for remedial action from any information, including any trend analysis." 21 C.F.R. § 803.53.

47. Manufacturers shall submit a written report to the FDA of any correction or removal within 10 working days of undertaking remedial or corrective action if the correction was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health. 21 C.F.R. § 806.10.

5. Medical Device Manufacturer Duty to Issue Recalls

48. "Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective." 21 C.F.R. § 7.40(a). Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of

the Food and Drug Administration. 21 C.F.R. § 7.40(b). A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations. *Id.*

49. However, in order for the FDA to make such determinations to request a recall or pursue other enforcement action, the FDA must have knowledge of the risk of injury, gross consumer deception, or danger to public health and welfare. For the FDA to have such knowledge and to achieve the FDCA's goals to provide for the safety and effectiveness of medical devices, the FDA relies on device manufacturers to adhere to their mandatory duties to report adverse events and corrective actions.

TOTAL KNEE REPLACEMENT BACKGROUND

A. Primary and Revision TKR

50. A patient's first TKR surgery is referred to as a "Primary Knee Replacement."

51. Because the conditions that lead to a patient having a TKR – namely osteoarthritis – primarily impact the elderly, over 60% of TKR surgeries are performed on patients over the age of 65.[5] A typical elderly patient undergoing a major surgical operation incurs significant attendant healthcare costs, including an average 4.2 day in-patient hospital stay (this estimate is for Primary TKR patients who receive the Exactech Optetrak system specifically)[6], follow-up visits and extensive outpatient rehab and physical therapy.

52. In 2009, 227,587 Medicare beneficiaries received a Primary TKR; the average Medicare payment for only the in-patient portion of the procedure (including the implant) was

[5] Li, Yu; et al. Variation of Medicare payments for total knee arthroplasty; The Journal of Arthroplasty Volume 28, Issue 9, 1513-1520 (October 2013). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3795823/

[6] Edwards J, Gradisar I Jr, Nadaud M, Kovacik M, Askey M. Eight and one-half year clinical experience with the Optetrak total knee prosthesis. Presented at the American Academy of Orthopaedic Surgeons. February 2004

$13,464.[7] In-patient costs for Primary TKR procedures rose to over $19,000 during 2012 and 2013.[8] By 2015, 431,199 Medicare patients underwent knee replacement surgery.

53. If a patient who already received a primary TKR experiences problems with that operation or implant, such as a device malfunction or device failure, then it may be necessary to perform a "Revision TKR." Revision TKR is a much more intensive operation than a Primary TKR as the intra-operational procedures are more complex to remove the Primary TKR and insert a larger and heavier Revision TKR implant.

54. Due to increased severity of a Revision TKR, the cost of Revision TKR procedures is greater than the cost of Primary TKR procedures. In 2009, the average Medicare payment for Revision TKR was $17,331, nearly 30% greater than average reimbursement for a Primary TKR. As with Primary TKR procedures, Medicare is by far the largest payor of Revision TKR operations and attendant inpatient and outpatient costs – in a sample of Revision TKR operations conducted in 2005-2006, Medicare was the primary payor for 59.5% of revision TKR procedures.[9]

55. These greater costs include a more expensive implant. Exactech's Optetrak Revision tibia tray costs between $1,300-2,000 whereas the Optetrak Finned Tray used in Primary TKR costs roughly $1,100.

56. One reason that a Primary Knee Replacement device can fail and require a Revision procedure is if the tibia component of the TKR device becomes loose – referred to as a "tibial

[7] *Id.*

[8] Weeks, William B.; et al. Episode-of-Care Characteristics and Costs for Hip and Knee Replacement Surgery in Hospitals Belonging to the High Value Healthcare Collaborative Compared with Similar Hospitals in the Same Health Care Markets. Medical Care Volume 55, Number 6 (June 2017). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5432098/

[9] Bozic, Kevin J.; et al The Epidemiology of Revision Total Knee Arthroplasty in the United States, Clinical Orthopedics and Related Research. Volume 468, Issue 1 pg. 45-51 (January 2010) available at: https://link.springer.com/article/10.1007/s11999-009-0945-0

loosening"—when the keel of the tibia tray, which is anchored to the patient's tibia, becomes loose and wobbles at the point of contact where the mechanical knee meets the patient's bone structure.

B. Average Revision Rates of Cemented Total Knee Replacements

57. "Revision surgery remains the benchmark outcome by which survival of orthopedic implants is assessed."[10] Most aggregate data that allows for assessment of the rate of TKR revision surgeries is found in National Joint Registries. Eleven countries maintain mandatory National Joint Registries and track every orthopedic device and its' outcomes, including the United Kingdom, Sweden, New Zealand and Australia. Orthopedic groups in the United States have recently taken strides to establish a national joint registry and published its first annual report in 2013. However, reporting to the American Joint Replacement Registry is voluntary and thus does not capture an encompassing view of joint replacement procedures. Established National Joint Registries demonstrate that a risk of revision surgery following a primary Total Knee Replacement for Osteoarthritis (the diagnosis encompassing over 83% of Primary TKRs) at 10 years post-operatively is roughly 5%.[11] At five years post-operatively, the standard rate of revision for Primary TKA for patients that underwent the primary surgery in 2008 was 3%.[12] Further, over 90% of modern TKR devices are still functioning well 15 years after the primary surgery.[13]

58. The Australian joint registry determined that the Optetrak knee had the worst failure rate of any implant on the Australian market. As a result, the Australian tax-payer funded health care system (also called "Medicare") no longer pays for the Optetrak TKR because of its unreasonable and outlier failure rate. However, the data assessed by the Australian joint registry

[10] M. Khan, et al. The epidemiology of failure in total knee arthroplasty: Avoiding Your Next Revision. *Bone Joint J* 2016;98-B (1 Suppl A):105-12

[11] *Id.*

[12] *Id.*

[13] American Academy of Orthopedic Surgeons, Total Knee Replacement available at: http://orthoinfo.aaos.org/PDFs/A00389.pdf

viewed all Optetrak Tibia models, and thus still minimized the true failure rate of the Optetrak with the Finned Tray.

59. Relator Manuel Fuentes, M.D., has in-depth knowledge of the industry standards of orthopedic device survival rates. A revision rate of 5%, or correspondingly a 95% survival rate at 10 years, is viewed as industry-standard among orthopedic device manufacturers. The industry standard is that a total knee replacement device with a revision rate of more than five percent at five years post-operatively signals that the device has some type of serious problem and represents unreasonable risk of substantial harm to the public health. Further, orthopedic industry-standard holds that when revision rates of greater than five percent at five years post-operatively occur, the company has a duty to alert the FDA and likely issue a recall.

THE OPTETRAK TKR

A. Excessive Business Risk of Exactech's Optetrak Products

60. The Optetrak TKR system was released in 1994 and has been Exactech's largest product line since the company began selling implants. In 2007, Exactech's Knee Division accounted for $63.4 million of its total revenue of $124.2 million, or 51% of total revenue. Within the Optetrak product line, Exactech only had two options for tibia trays until 2011: (1) the defective Finned Tibia Tray and (2) the "Trapezoid" Tray, which was used as the revision system.

61. Having only one product line with only one Primary Knee Tibia Tray (and only one Revision Tibia Tray model) is an extremely narrow product line and a significant aberration from standard orthopedic device industry practice. For instance, Exactech's competitor Stryker has over a dozen different knee models from which to choose. A major reason orthopedic device companies have multiple lines for a given implant and typically multiple – interchangeable – components within that product line is because if the company realizes that there is a problem with a component

or even a particular product line, the company can remove the problematic component or product from the marketplace without destroying its entire revenue source.

62. This over-reliance on one component (the Finned Tibia Tray) within one product (Optetrak TKR) created an excessive risk situation beyond the standard business-risk confronting an orthopedic device company.

63. Exactech's excessive business risk was further amplified because of Exactech's mismatched implant sizing and high cost inventory strategy. Based on this excessive risk, Exactech was poorly positioned to deal with a potential recall and ultimately determined that it would avoid a recall at all costs, even if that meant committing fraud.

64. Because of this excessive risk, when Exactech discovered that the Finned Tibia Tray Optetrak TKR was causing thousands of revision surgeries and failing at rates more than 10 times the industry standard, it was a catastrophic problem for the company. When the issue came up, Exactech distributor Timothy O'Neill summed it up best by saying that if Exactech had complied with its legal, ethical, and moral obligations and disclosed the Finned Tibia Tray failures, "the stock price would have dropped to sixteen cents overnight."

EXACTECH'S FRAUDULENT SCHEMES

I. Facts Demonstrating Exactech's Knowledge and Cover-up of the Finned Tray's Defects

A. Surgeons Report Finned Tibia Tray Optetrak TKR Failures to Exactech

65. The first known and substantial disclosure to Exactech of widespread Finned Tibia Tray Optetrak TKR failure was in 2007 or early 2008 from Exactech Distributor Timothy O'Neill, owner of Surgical Systems Inc. in Gorham, Maine and his primary orthopedic surgeon client, Dr. Wayne Moody. Dr. Moody – an orthopedic surgeon based in Auburn, ME – was the "keystone client" for Mr. O'Neill's company and began to have an increasing number of patients

experiencing significant tibial loosening problems with the Finned Tibia Tray Optetrak TKR. Overall, Dr. Moody had 51 patients with tibial loosening problems due to the Finned Tibia Tray's device failure. Each of the 51 patients required a revision surgery and was disclosed to Exactech. This high number of failures was unprecedented in Dr. Moody's experience and upset him greatly. Accordingly, Mr. O'Neill and Dr. Moody made a detailed presentation – including an intra-operation film – to Exactech. Mr. O'Neill was then assured by Exactech that it would put together a "committee" to address the failures.

66. Exactech's response to Mr. O'Neill and to Dr. Moody (and effectively to the 51 patients whose knee replacement devices came loose and required a major secondary surgery) was that Dr. Moody was the only surgeon from whom they were hearing of these device failures and that the problem was not with the Finned Tibia Tray but instead with Dr. Moody's "cement technique."

67. Surprisingly, Dr. Moody remained a loyal customer of Exactech joint replacements despite 51 of his patients experiencing device failures and Exactech's attempting to blame Dr. Moody himself for the failures. The explanation for Dr. Moody's loyalty is that Exactech offered Dr. Moody a "consultant agreement." For instance, in 2012, Exactech paid Dr. Moody $11,870 for "Research/Clinical studies support." Relators have knowledge that Dr. Moody received even more substantial consulting payments prior to 2012 and that the consulting agreements required little to no effort on Dr. Moody's part other than that he continue to use Exactech products. Exactech also hired Dr. Moody's son as an Exactech sales representative – further securing Dr. Moody's allegiance to Exactech through illegal *quid pro quo* remuneration for Dr. Moody's continued business.

68. Relators are aware of several other physicians whose patients experienced tibial loosening problems requiring revision surgeries due to the Finned Tibia Tray's design defects and who reported these device failures to Exactech around this same time – most concentrated in the latter half of 2007. Randy Hebert, the largest Exactech distributor in the United States, based in Ocala, Florida and with sales territory throughout Florida, dealt with numerous surgeons who saw patients experience tibial loosening due to the failures of the Finned Tibia Tray in the Optetrak TKR. Mr. Hebert's territory is the largest volume territory in the United States – often selling more than $20 million annually in Exactech products. Despite the complaints from Mr. Herbert's physician clients, Exactech falsely maintained to Dr. Moody that he was the only surgeon experiencing failures with the Finned Tibia Tray.

69. When Mr. O'Neill began experiencing problems with Dr. Moody's patients in Maine, he contacted Mr. Hebert, who informed him that around the 2008 time period "everyone was calling him" – meaning Mr. Hebert's high-volume surgeons were calling him reporting major problems with tibial loosening events due to the Finned Tibia Tray.

70. The following physicians are clients of Mr. Hebert who reported their patients experiencing abnormal tibial loosening problems with the Finned Tibia Tray to Mr. Hebert: Dr. Raymond Robinson, in Miami, FL; Dr. Ross Stone in Lake Worth, FL; Dr. Morton Bertram in Naples, FL; Dr. Nicholas Connors in Punta Gorda, FL; Dr. Kirk Maes in Sebastian, FL; Dr. Robert Love in Palm Bay, FL and Dr. David Kreisberg in Melbourne Beach, FL.

71. Another surgeon who reported significant tibial loosening events was Dr. Shekhar Desai, based in Palm Bay, FL. When Dr. Desai reported that he was seeing patients with early-onset tibial loosening – within six to twelve months of implantation – Relator Manuel Fuentes was

sent as the Exactech surgeon liaison to personally help Dr. Desai. Together, Relator Fuentes and Dr. Desai reverse engineered a "quick-fix" to attempt to remedy the Optetrak Finned Tibia Tray's flaws.

72. This "quick fix" involved using significantly more cement than the Exactech instructions called for to secure the Finned Tibia Tray by creating "wider wings" in the keel of the Finned Tibia Tray with cement. These wider cement wings created a circumferential cement mantle around the keel and provided the necessary stability to sufficiently anchor the Finned Tibia Tray. Eventually, Dr. Desai refused to use the defective Finned Tibia Tray despite Exactech's attempts to provide a "quick-fix." Because of his large patient volume and status as a preferred surgeon, Dr. Desai was provided with the trapezoid tray, the much-larger tray that should have been used only for Revision TKR surgeries. Dr. Desai was also a well-paid Exactech consultant, which was at least one reason for his continued purchase of Exactech products despite his knowledge that Exactech's primary product was woefully defective.

73. Dr. Kyle C. Swanson is another example of a long-time Exactech consultant surgeon who refused to use the Finned Tray because of his knowledge of its defects and was instead provided with the Revision system Trap Tray for Primary TKR surgeries. Using the Revision TKR components for Primary TKR procedures meant more bone had to be removed from patients than was necessary, patients endured more significant recoveries, and they would never have the range of motion and mobility an actual Primary TKR device would have provided.

74. During the 2007-2008 time period, Kevin Bouley, an Exactech distributor based in the Boston, Massachusetts metro area, informed Tim O'Neill that one of his orthopedic surgeon customers – Dr. Chris Hutchins, based in New Haven, Connecticut – also had 35 patients implanted with the Optetrak Finned Tibia Tray who experienced tibial loosening events, indicative of a

device failure, and required revision surgeries. When Mr. Bouley reported this to Exactech, the Company's leadership falsely told him (as it told all others) that he was the only distributor with a physician experiencing tibial loosening events associated with the Finned Tibia Tray Optetrak TKR.

75. Relators also have knowledge that Dave Vandermosen, a former Exactech distributor in the Georgia territory, had relationships with several surgeons whose patients experienced tibial loosening events associated with the Finned Tibia Tray. These surgeons included Dr. Scott Gillogly in Atlanta, GA, Dr. Freddy Achecar in Douglasville, GA, Dr. David Covall in Cumming, GA, Dr. Jon Minter in Alpharetta, GA and Dr. John Doris in Athens, GA. Exactech repeated the standard line to all of them: that they were the only surgeons whose patients were experiencing the device failures.

B. Exactech's Investigation of the Tibial Loosening Issues

76. Exactech engaged Dr. Ivan Gradisar to perform an audit of patient outcomes and develop a better understanding of the severity of the tibial loosening problem. Dr. Gradisar's audit is attached as Exhibit A. This audit included a comprehensive review of patients from the Summa Health System Hospital in Akron, Ohio, who received a revision knee replacement surgery during a seventeen-month period between January 1, 2004 and May 5, 2005 and a fifteen-month period between January 1, 2007 and April 1, 2008.

77. Dr. Gradisar's audit excluded specific patients from being reported as "Loose Exactech Tibial Trays" yet provided enough information that upon review that Relator Dr. Manuel Fuentes immediately recognized certain patients' revision surgeries were due to a loose Exactech tibial tray yet were not reported as such. Furthermore, several patients had both knees replaced with Exactech Optetrak TKR devices and both knees failed due to tibia loosenings – however, Dr.

Gradisar only reported these patients as one loosening or did not categorize these failures as due to tibial loosening.

78. Of the 47 patients who received a TKR revision surgery between January 1, 2007, and March 31, 2008, Dr. Gradisar opined that 12 patients required revisions due to loose Exactech Finned Tibial Trays. Dr. Gradisar also categorized 10 of the 47 revisions as "Infected Requiring Revision." This is a misleading presentation of data because often knee replacements become infected due to loose components, most often a tibial tray loosening. Another four revisions of Exactech Finned Tibial Trays were attributed to a "broken tibial spine," which is also a secondary condition usually caused by a loose tibial tray. Further, Dr. Gradisar only categorized 33 of the 47 charts he reviewed, leaving many questions about the validity of his investigation. Nevertheless, a review of his patient summaries shows, in his self-selected sample, at least 24 Exactech Finned Tibia Trays failed, requiring a revision, due to tibial loosening events or tibial loosening related problems.

79. Many of Dr. Gradisar's remarks demonstrate the severity of the tibial loosening problem. One example, for Patient M.T., provides "11/22/06 [the date of the primary TKR surgery] OPTETRAK, RIGHT/LEFT PS CEMENTED…1/5/07 [date of revision surgery] – PL [Surgeon Phillip Lewandowski] REVISED BOTH TIBIAS…CCK [Constrained Congular Knee] CEMENT/BONE LOOSENING…BOTH IN VARUS. This notation means that Patient M.T. received a double Optetrak TKR and within approximately six weeks the tibia portion of both knees had loosened to the point that the tibia tray stem was "in varus" - meaning at a crooked angle and not aligned with the tibia. This tibial loosening required Exactech consultant surgeon Phillip Lewandowski to revise both of Patient M.T.'s knees to a Constrained Congular Knee, which is the most restrictive and thickest anchoring knee replacement device and requires an extensive amount

of bone to be removed to secure the tibial anchoring device. However, patient M.T. was not classified as one of the "tibial loosening" patients in Dr. Gradisar's results. Relator Dr. Manuel Fuentes reviewed this description of Patient M.T.'s chart and believes Patient M.T.'s double knee revision within six weeks of primary surgery was clearly related to tibial loosening problems and would have been reported as such in a more objective audit.

80. Dr. Gradisar also provided a description of his audit, methods, and his opinion of the causes of the tibial loosening issues. Dr. Gradisar begins "I have taken the list of all knee revisions at Summa done between 7/1/07 and 4/1/08 supplied by Mosher Medical [the Exactech distributor in the Akron, Ohio area] and reviewed the office charts looking for information regarding a possible tibia loosening issue." Dr. Gradisar continues: "I believe the issue has multiple causes and the order of significance may be different for each surgeon or even each patient." Dr. Gradisar then lists three cosmetic causes of the tibial loosening issue, the first of which becomes Exactech's primary excuse for the tibial loosening problem: problems with the surgeon's cement technique. The second and third causes are equally cosmetic and innocuous: 2. "never fail in varus particularly on the tibia" and 3. "avoid doing the morbidly obese patients." However, the fourth listed cause for the tibial loosening problem is "some implants may have a greater margin of error than others…"

81. Dr. Gradisar then describes basic orthopedic surgery protocol as "certain precautions that tilt the odds [against tibial loosening and device failure] favorably." Yet, in a recommendation to do more than follow basic orthopedic standards to "tilt the odds of device failure favorably," Dr. Gradisar opines: "It may be possible to design a stem that is more forgiving, avoid features that lead to canal pressurization but develop a secure initial mechanical fit." In other words, the design of the Finned Tibia Tray "may be" flawed.

82. Despite the couched language, and the short-comings of Dr. Gradisar's patient audit, his report clearly provided Exactech with more than enough information to recognize that the Optetrak Finned Tibia Tray was failing at alarming rates well outside the industry norm.

C. Exactech's Identified Causes of Tibial Loosening Device Failure

83. As part of the internal investigation into the reports of tibial loosening problems and mounting revision surgeries, Exactech engineers examined the suspected causes of the tibial loosening events. Relator Manuel Fuentes was actively involved in this investigation in which several design engineering flaws were identified as potential causes of the tibial loosening problem.

84. First, Exactech discovered specific flaws in its own engineering process related to the sizer used for the Exactech Finned Tibia Tray, which contributed to the tibial loosening problem. Early in the trial phase of the Optetrak system, the design team – including Raymond Cloutier and Albert Burnstein – realized the Optetrak knee was not able to extend fully. To remedy this problem, the design team instructed to cut more of the femur bone away to create more space to allow for the proper flexing of the joint. As the team sought to create a symmetrical fit into the gaps in the bone that are made to fit the implant, the sizer had to also be adjusted to size for this extra space. The way Exactech accounted for the extra space required for full movement was to create what was referred to as the "fudge factor," in which the sizer was intentionally made to be slightly inaccurate to "size down" the femoral component by a half size to create the extra room needed for full range of motion. With this adjustment, if a patient's femur was a size three, the sizer measured it as a size 2.5. In this common situation, when a patient measured at a half-size, Exactech recommended downsizing the smaller available size – which in this example would yield a patient measuring at a size two. This design flaw was not a problem until Exactech developed

the Low Pressure Instrument 2 (LPI 2) in mid-2006 to replace the earlier LPI 1 system that featured the fudge factor described above.

85. A relatively new engineer, Trevor Schluetter, was the primary designer of the LPI 2 sizer instrumentation. Mr. Schluetter was not with Exactech during the design phase of Optetrak and LPI 1. When Schluetter embarked to design the LPI 2, no one from Exactech informed him that the LPI 1 had this built-in hidden "fudge factor" and therefore Schluetter designed the LPI 2 to size accurately the femur without the "fudge factor." As a result, there was a large increase in size 3 femur 2 tibia (3F/2T) devices. The dimensions of the size two tibia corresponded to the size of the keel of the 2F/1T and 2F/2T tibial components, which was significantly smaller than the size three tibia keel. This production process failure, which resulting in the Optetrak Finned Tibia Tray device failures using the LPI 2 sizer, was in violation of current Good Manufacturing Practices. *See* 21 U.S.C. § 360j(f).

86. With this smaller anchorage in the tibia being required to support the more substantial loads of a size three femur, the anchoring keel would wobble, creating a "see-saw" effect and eventually cause the tibia tray to become loose. While tibial loosening problems necessitated revision surgeries in all sizes of Optetrak knee replacement devices, this sizing problem led to widespread failure in size 3 femur, size 2 tibia devices. In fact, Relator Fuentes believes that the size 3F/2T tibia devices failed almost invariably. He reported this problem to his superiors, who continued to sell the flawed device and did not report it to the authorities, in violation of 21 C.F.R. § 803.53 — which requires reporting the need for remedial action.

87. Therefore, because of this engineering process and manufacturing failure, the Optetrak devices implanted after mid-2006 (with the LPI 2 sizer) were a materially different device than the Optetrak devices implanted prior to mid-2006 (with LPI 1 sizer) that had been approved

by the FDA upon the launch of the Optetrak product line in 1994. One sizer tool, the LPI 1, sized patients' bones accurately, and due to Exactech engineering process and manufacturing failures, the LPI 2 sized patients' bones inaccurately and caused widespread tibial loosening problems. Further, the timing of the launch of the defective LPI 2 in mid-2006 corresponds with the deluge of tibial loosening events and revision surgeries starting in 2007. Another factor that compounded the problem was that the "punch" tool used to make the hole to "seat" the tibia tray in the bone came in only three sizes: size 1 and 2 tibias used the same size punch tool, size 3 and 4 used the same punch, and size 5 and size 6 shared the same punch. Therefore, when the sizing became distorted with the introduction of the LPI 2 instrumentation, an actual size 2 tibia could be sized as a size 3 and therefore the seating hole would be punched with the size 3 / size 4 punch – which created a hole actually large enough to seat a size 4 tibia and thus created a hole far too large for the actual size 2 implant.

88. Yet another cause of the Finned Tibia Tray tibial loosening events involved a change in the coating material used to cover the exterior of the Finned Tibia Tray. This cause was presented by Tim O'Neill when he and Dr. Moody made their presentation to Exactech about the tibial loosening problem in 2007. Mr. O'Neill, as well as Exactech engineers upon their investigation, noticed that the cemented portion of the early Exactech Finned Tibia Trays were covered with a gritty, porous coating – achieved through a "sand-blasting" process. However, the later tibia trays that were examined as part of tibial loosening investigation had a much shinier, polished surface finish. Exactech engineers and surgeons alike believed that this polished surface finish did not hold to the surgical cement well and caused the tibial tray to become loose. Therefore, the Exactech Finned Tibia Tray with the gritty, porous coating performed by sandblasting, which was approved by the FDA upon the product launch in 1994, was a materially

different device than the later, post-2006 devices that exhibited the shiny, polished finish. By not addressing, remediating, or disclosing the change in coating, Exactech violated the cGMP regulations and requirements to disclose the need for remedial action to prevent an unreasonable risk of substantial harm to the public health—rendering the device "adulterated" and "misbranded." *See* 21 U.S.C. § 360j(f); 21 C.F.R § 803.53

89. There were other causes identified as well, including a manufacturing defect that caused the device's forgings to be a different shape to the actual implant. Due to this manufacturing defect, the tibial tray was unable to seat completely, causing it to more easily become loose. By not addressing, remediating, or disclosing the problems with the shape of the forgings, Exactech violated the cGMP regulations and requirements to disclose the need for remedial action to prevent an unreasonable risk of substantial harm to the public health—rendering the device "adulterated" and "misbranded." *See* 21 U.S.C. § 360j(f); 21 U.S.C. § 352(t).

90. Further, Dr. Gradisar, in his description and summary of his audit, opined that the blunt, rounded nose of the Finned Tibial Tray could increase fat "blow-back" as the tibial stem was inserted into the tibia. This slippery fat then covered the surface of the tibial stem and contributed to conditions for tibial loosening. This feature was ultimately changed when Exactech released its "Fit" Tray – the successor to the Finned Tray – as the Fit Tray featured a flat nose.

91. The general consensus within Exactech was all of these design and manufacturing problems created a "perfect storm" of issues – each contributing to the widespread tibial loosening issues. However, as the tibial loosening problem became undeniable, Exactech management ceased further investigation into the specific causes of the failures and proceeded to focus on cover-up efforts.

92. Several of these identified problem issues were specifically addressed and changed in the replacement Fit Tray – demonstrating that Exactech was aware of the problems but sought to correct them in secret – in violation of 21 C.F.R. § 806.10 – because Exactech did not submit a written report to the FDA of these corrections within 10 working days. *See* 21 C.F.R. § 806.10. For instance, the implant's material was switched from a Titanium alloy to Cobalt–Chromium alloy, which was a stiffer material designed to be more adhesive with bone cement, the Fit Tray had a flat nose instead of a round nose like the Finned Tray to minimize fat blow-back, and the surface roughness in the Fit Tray was also altered to be a rougher, more gritty surface that was designed to enhance cement interdigitation into the implant.

D. Exactech's Decision to Conceal the Device Failures

93. In early 2008, based on the widespread reports of significant device failure, mounting revision surgeries, and Dr. Gradisar's tacit substantiation of these reports, Exactech had definitive knowledge that the Exactech Finned Tibia Tray was defective. Exactech formed an investigatory committee to determine the causes and develop potential plans of action to address the widespread device failures. As a Senior Product Manager, Relator Manuel Fuentes was an integral part of this investigatory committee and personally attended these meetings. Other participants in these committee meetings included the leading engineers, product managers, and executives within Exactech, including Dr. Bill Petty, founder and then-CEO; Dr. Gary Miller, founder; Raymond Cloutier, Vice President of Research and Development; Alan Siedel, Chief Knee Engineer; Charley Rye, Director of Marketing; Xavier Sarabia, Vice President of Regulatory and Clinical; and Jodie Phillips, Chief Financial Officer.

94. Charley Rye, Director of Marketing, proposed the logical, natural, and legal solution to issue a recall, pull the finned tray inventory from the market, and replace it with the

Revision TKR's Trap Tray. It was acknowledged that this plan of action would be financially detrimental to the company, but it was Exactech's only legally-compliant option because the Finned Tibia Tray was the only primary TKR tibia tray Exactech produced.

95. Jody Phillips, Chief Financial Officer, then stood up and proclaimed that recalling the Finned Tray was not an option because it would be too financially detrimental to Exactech. Phillips explained that Exactech was "drowning in [Finned Tray] inventory" and the company could not afford to absorb the inventory cost. Further, Phillips stated that there was not enough Trap Tray inventory and that the cost would be too high to ramp up production of enough Trap Trays to meet the demand needed to replace the Finned Tray. Phillips's position was that if Exactech adhered to its legal and ethical obligations and disclosed the Finned Tray failures, the financial damage to the company would be too great, and thus disclosure of any kind was not a viable financial option for the Company.

96. Xavier Sarabia, Exactech Vice President of Regulatory and Clinical, the Executive who was ostensibly charged with regulatory and legal compliance, did not object to Phillips's plan, which would obviously result in organization-encompassing fraud. Instead of insisting that the company disclose the Finned Tibia Tray problems, Sarabia highlighted regulatory requirements that – if followed – could lead to suspicion and be problematic for the cover-up.

97. Specifically, Sarabia stated that the mounting revisions could become a problem because the FDA requires each revision that may have been caused by the device to be reported, the device returned and paperwork submitted to the FDA. If Exactech followed the requirements, the hundreds of ensuing revisions and accompanying reports would certainly raise red flags and would be indicative of device failure. As detailed herein, the statutory and regulatory requirements Sarabia was referring to are 21 U.S.C. § 360(i), 21 C.F.R. § 803.5, and 21 C.F.R. § 803.53, and

they do, in fact, require medical device manufacturers to report individual adverse events that may have been caused by the device, including knee replacement revision surgeries. 21 C.F.R. § 803.5.

98. Accordingly, Exactech knew it was required to disclose these precise problems to the FDA and was required to produce to the FDA the reports from its distributors of Finned Tibia Tray failures, including Tim O'Neill's and Dr. Moody's presentation and Dr. Gradisar's audit. After acknowledging these requirements, the top executives of Exactech decided to disregard these FDA reporting requirements, actively conceal this information, present affirmative false statements and misleading half-truths to the FDA, and continue to lie to surgeons in order to sell the defective Optetrak Finned Tibia Tray – thereby knowingly causing false claims for payment to be made to government health care programs and untold harm to its patients, including U.S. military veterans and the elderly.

II. Examples of False Statements and Records Made by Exactech That Are Material to False Claims

A. Exactech Misled the FDA and Rendered the Opterak Misbranded by Failing to Submit Adverse Event Reports

99. Exactech learned of 51 separate reportable events from one surgeon, Dr. Wayne Moody. Dr. Moody and Tim O'Neil presented a full presentation, including intra-operative film, to Exactech's corporate officers detailing the reportable device failures. Mr. O'Neil and Dr. Moody further informed Exactech of the suspected cause of these failures: that there was a change in surface coating from earlier Optetrak Finned Trays that was causing the tibial components to come loose. Despite this reportable information, Exactech did not report these adverse events in violation of the FDA reporting requirements. *See* 21 U.S.C. § 360i; 21 C.F.R. § 803.50; 21 C.F.R. § 803.53.

100. Similarly, each of the 35 revision surgeries due to Finned Tray device failure reported by Dr. Hutchins, and the plethora of revision surgeries reported by the above-referenced surgeon clients of Randy Hebert and Dave Vandermosen, each required an adverse event report be submitted by Exactech to the FDA. Exactech knowingly concealed these revision surgeries.

101. Further, Dr. Gradisar's report, received by Exactech on or around April 1, 2008, also provides more than enough information to trigger Exactech's obligation to submit a report to the FDA regarding the identified revision surgeries because Exactech became aware of information that reasonably suggests that the Optetrak TKR, and specifically the Finned Tibia Tray, "may have caused or contributed to a serious injury." *See 2*1 U.S.C. § 360i; 21 C.F.R. § 803.50. Dr. Gradisar's report specifically says, regarding the tibial loosening issue: "I believe the issue has multiple causes and the order of significance may be different for each surgeon or even each patient." One of the listed causes is then "some implants may have a greater margin of error than others." Further, even if relying on Dr. Gradisar's other reasoning for the tibial loosening events, it is clear that—at minimum—the Finned Tibia Tray is an indirect cause of the adverse event and triggers reporting obligations. *See* 21 U.S.C. § 360i; 21 C.F.R. § 803.50.

102. Moreover, the Gradisar audit and report provided more than enough information to Exactech that the Finned Tibia Tray had "malfunctioned and this device or a similar device would be likely to cause or contribute to a serious injury, if the malfunction were to recur." *See* 21 U.S.C. § 360i; 21 C.F.R. § 803.50. This knowledge mandated that Exactech submit not only the delineated information in FDA Form 3500A, but also "any information in [Exactech's] possession" – clearly encompassing Dr. Gradisar's audit and report in its entirety. 21 C.F.R. § 803.50; 21 C.F.R. § 803.52. Instead, they sequestered Dr. Gradisar's findings and initiated a large-scale cover-up and disinformation campaign.

103. By highlighting the significant device failures and by recommending as a solution that Exactech "design a stem that is more forgiving," Dr. Gradisar's report informed Exactech that remedial action was necessary to "prevent an unreasonable risk of substantial harm to the public health." Accordingly, Exactech was required to submit a report to the FDA within 5 days of receiving this information. *See* 21 C.F.R. § 803.53. While they began working on a new design, Exactech never submitted the report to the FDA and continued to sell the Optetrak TKR.

104. In violation of the above-referenced FDA reporting requirements, specifically 21 U.S.C. § 360(i), 21 C.F.R. § 803.50, 21 C.F.R. § 803.52, and 21 C.F.R. §803.53, Exactech did not report any of the tibial loosenings or revision surgeries identified in Dr. Gradisar's audit. By virtue of these reporting violations, the Exactech Finned Tibia Tray was misbranded. *See* 21 U.S.C. § 352(t). As a result of this significant and knowing violation of FDA reporting requirements which created a risk to public health, the Finned Tray could no longer be marketed in the United States. *See* 21 U.S.C. § 333(f); 21 U.S.C. § 331.

B. Materially False Statements, Half-Truths and Misleading Information Contained in Adverse Event Reports that Exactech Did Submit

105. In 2008, Exactech reported 18 separate Adverse Events related to the Optetrak TKR system to the FDA. Relators have knowledge of at least 100 revision surgeries directly resulting from Finned Tibia Tray loosening events – not even including the deluge of revisions in the highest-volume territory in Florida (where revisions were known to be rampant). Exactech's reporting of only 18 adverse events in 2008 was a knowing violation of the reporting requirements and materially misled the FDA.

106. It was not merely the lack of adverse event reports submitted by Exactech that constituted an intentional deception of the FDA, but also the materially false statements, half-truths, and misleading information contained within the reports that were submitted. Each of the

18 reports submitted in 2008 were materially false and misleading both by affirmative misrepresentation and by omission. For example, Report Number 1038671-2008-00035, submitted to the FDA on August 15, 2008, was the first report filed by Exactech after receipt of Dr. Gradisar's April 1, 2008, audit. This Report regards an "Optetrak Cruciate Retaining Tibial Insert" and the event description provides: "A total knee arthroplasty was revised approximately one month post operatively, due to a report of wear." In this report, Exactech makes the affirmative false statement that the report is not a Product Problem Report.

107. The next adverse event report submitted by Exactech related to the Optetrak system was submitted to the FDA on November 14, 2008 and provided that it regarded a "Cemented Finned Tibial Tray" – precisely the device that at the time was prompting repeated complaints by multiple surgeons and an internal audit by Exactech. The event description provided was "Revision of tka due to tibial loosening" – precisely the issue that Exactech knew was causing hundreds of other preventable revision surgeries. Yet, Exactech falsely represented to the FDA that the Report was only an Adverse Event Report, while affirmatively and falsely stating it was not a Product Problem Report.[14] Exactech also did not provide an answer to the question "Was Device Evaluated by Manufacturer?"[15] The short answer to that question was: "Yes." The complete answer was: "yes, and the evaluation demonstrated an unusually high failure rate suggestive of a flaw." Exactech never filed a supplementary report nor provided an answer to this or the other unanswered questions in this initial report, in violation of 21 C.F.R. § 803.50(b)(3).

[14] MAUDE Adverse Event Report: EXACTECH, INC. OPTETRACK CEMENTED FINNED TIBIAL TRAY. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=1240807&pc=HSH (last visited January 23, 2018)

[15] *Id*.

108. Similarly, Exactech submitted another Adverse Event Report regarding the Optetrak Cemented Finned Tibial Tray on November 21, 2008, and provided the following event description as if it were an anomaly even though it was characteristic of hundreds of other tibial loosening events: "A total knee arthroplasty (tka) was revised approx. 14 months post operatively, due to loosening."[16] Again, in this Adverse Event Report and all other Reports submitted in the same 2007-2008 timeframe, Exactech made material false statements that the adverse events were not related to a Product Problem, and it pervasively omitted any information that would alert the FDA that Exactech had conducted an internal investigation that resulted in Exactech recognizing that the Finned Tibia Tray had material design flaws and failed at an alarmingly high rate.

109. Tellingly, none of the Adverse Event Reports mention anything about the surgeon's "cement technique" – which was the pretextual explanation Exactech provided to complaining surgeons.

C. Exactech's Claimed Optetrak Finned Tray Survival Rates Were False and Rendered the Optetrak Finned Tray Misbranded

110. Despite its' uncontroverted knowledge that the Exactech Finned Tibia Tray had major flaws, with a true survival rate of roughly 65-70% at three years, Exactech falsely represented and continues to falsely represent that the Exactech Optetrak system has a survival rate of 98.6% at 8.5 years and a survival rate of 99% at five years.[17] This false data was

[16] MAUDE Adverse Event Report: EXACTECH, INC. OPTETRAK CEMENTED FINNED TIBIAL TRAY. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=1242525&pc=HSH (last visited January 23, 2018).

[17] Optetrak- A Comprehensive Knee System; 712-01-21 Rev. D Optetrak Main Brochure 0410 (2010) available at: https://content.exac.com/wp-content/uploads/sites/3/2016/10/712-01-21_RevD_Optetrak_Main_Brochure.pdf

misleadingly cited in the Optetrak sales brochure – which is the primary marketing material for the Optetrak system – as well as throughout Exactech marketing materials.[18]

111. The 98.6% at 8.5 years survival rate propounded by Exactech is based on a non-published, non-peer-reviewed presentation made in 2004 by Dr. Ivan Gradisar – the same surgeon who performed the misleading and hidden patient audit in April 2008 that demonstrated major problems with the Exactech Optetrak system.[19] Dr. Gradisar is also listed as one of six members of the Optetrak Design Team and therefore receives significant royalties based on sales of the Optetrak TKR. This non-published, non-peer-reviewed observation used a sample of 1,575 knees replacements performed on 1,201 patients in Dr. Gradisar's own practice from June 1, 1994, until February 2004.

112. This observation claims only 13 of 1,575 knee replacements required "re-operation" and only one re-operation was due to tibial loosening. However, in Dr. Gradisar's confidential audit of Exactech knee replacement patients in his practice four years later, he reports that at least 24 revision surgeries were required in his clinic due to tibial loosening events. Exactech hid this 2008 report, has not made any correction to the outdated and false data, and continues to knowingly and falsely propound the 2004 presentation as conclusive evidence that the Optetrak system has a 98.6% at 8.5 years survival rate – based on only one tibial loosening revision.

113. Further, this non-published, non-peer-reviewed observation surveyed Optetrak system devices implanted prior to 2004, which is prior to implementation of the LPI 2 sizer

[18] *See Id.*

[19] Edwards J, Gradisar I Jr, Nadaud M, Kovacik M, Askey M. Eight and one-half year clinical experience with the Optetrak total knee prosthesis. Presented at the American Academy of Orthopaedic Surgeons. February 2004.

instrumentation in mid-2006 and the change in the Finned Tray coating. Therefore, Dr. Gradisar's observation is entirely false and misleading because it provides survival data for the pre-2006 Optetrak TKR, not the materially different and defective post-2006 Optetrak Finned Tray TKR. Moreover, because Dr. Gradisar's 2004 non-published, non-peer-reviewed presentation lacks significant medical data such as the type of Optetrak Tibia Tray used, it is unknown what percentage of patients received the Trapezoid Tray as opposed to the defective Finned Tray.

114. The other study that Exactech relies upon for its claim that the Optetrak TKR Finned Tray has survival rate of 99% at 5 years post-operatively was conducted by Dr. Raymond P. Robinson – another longtime Exactech consultant and surgeon.[20] Dr. Robinson's study is based on a sample of 66 knee replacements in 47 patients.

115. Critically, Dr. Robinson's observation studied patients who exclusively received the Exactech Optetrak Trapezoid Tibial Tray, which was Exactech's larger, heavier tibial tray used as the revision surgery system and by all accounts was a functioning medical device, though not designed to be a Primary TKR device.[21] Therefore, no patient in this study, which Exactech has relied upon for years to proclaim a 99% survival rate for the entire Optetrak system, received the Finned Tibia Tray – which was used in the vast majority of Exactech Primary TKR operations and was the device known by Exactech to be defective.

116. Exactech has conducted a systematic fraud upon federal health care programs, the FDA, surgeons who use and bill for its products, and ultimately patients who have been and continue to be implanted with the flawed Exactech Finned Tibia Tray, by falsely conflating the

[20] Robinson RF. Five-year follow-up of primary Optetrak posterior stabilized total knee arthroplasties in osteoarthritis. *J Arthroplasty*. 2005 Oct;20(7):927-31.

[21] *Id. at 928 (*"The Optetrak Posterior Stabilized knee was used exclusively. A modular, titanium alloy metal-backed tibial component with trapezoidal cross-sectioned stem was used in all knees…included in this study.")

Optetrak line of TKR devices as one device despite using materially different tibial components – one that is functional (the Trapezoid Tray) and one that is defective (the Finned Tray). In so doing, Exactech has illegally marketed a misbranded medical device and due to such misbranding, all sales of the Exactech Finned Tibia Tray in the United States were illegal and all purchases of the Exactech Finned Tibia Tray by government health care programs represent false claims for payment. 21 U.S.C. § 352; 21 U.S.C. § 331.

1. True Finned Tibia Tray Failure Rate

117. Exactech has intentionally made it difficult to discern an accurate survival rate, or, more aptly termed, a failure rate, of the Finned Tibia Tray. Despite Exactech's reports to the contrary, the true failure rate of the Finned Tibia Tray is known by Relators (and Defendant) to be approximately 30-35% in the first three years. However, one study titled "Poor results of the Optetrak™ cemented posterior stabilized knee prosthesis after a mean 25-month follow-up: Analysis of 110 prostheses" (hereinafter "Thelu Article") was published in a peer-reviewed medical journal in 2012.[22] The Thelu Article, conducted by orthopedic experts and led by C.E. Thelu in France, surveyed 110 Optetrak Finned Tray prosthesis and within a mean follow-up time of 25 months. In that short time, 13 of the prostheses required revision.[23] Nine revisions were specifically for early loosening of the tibial component and at the end of the mean two-year time period, another 10 patients remained with pain and "presented worrisome radiological and clinical signs indicating loosening or patellofemoral impingement[]" – meaning revision would be likely.[24]

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[22] C.-E. Thelu, et al. "Poor results of the Optetrak™ cemented posterior stabilized knee prosthesis after a mean 25-month follow-up: Analysis of 110 prostheses" Orthopaedics & Traumatology: Surgery & Research (2012) **98**, 413—420.

[23] *Id* at 416.

[24] *Id.*

This study found the cumulated survival rate at 36 months for the Finned Tibia Tray Optetrak was 80.97 ± 9.1% and 76.74 ± 12% at 45 months.[25]

118. Despite pointing out the major flaws with the Finned Tibia Tray, primarily "early tibial loosening at the tibial tray – cement interface" and debunking Exactech's claimed reason for tibial loosening, "surgical technique [in context of cement] has not evolved compared to the original Insall implant (Ib II and its successor), which, at the same follow-up time, had not led to this type of problem," Thelu's article still missed the crucial point that has allowed Exactech's long-running fraud.

119. Thelu's article states: "Our revision rate with this implant is much higher than what has been reported by other teams with the *same prosthesis"* (emphasis added). The Thelu Article then cites to the 2005 Dr. Robinson study finding 99% survival rate of the trapezoid tibial component and a 2011 study by Dr. Robinson observing only the all-polymer Optetrak tibial component (not the metal Finned tibial component) which found a 97% survival rate at a mean of 11.6 years.[26] These compared revision rates pertain to different prosthesis as the studies assessed different tibial components with wildly different efficacy – one defective and two functional.

120. Relators have specific, independent, and non-public knowledge of approximate failure rates of the Finned Tibia Tray in the United States. From August 2011 to April 2014, Dr. David Lemak performed roughly 215 Primary TKR operations using the Optetrak Finned Tray, a considerable statistical population size. Of those 215 Primary TKR operations, Dr. Lemak had to revise roughly 25%, performing 55 revisions as of July 2017 – all due to tibial loosening events.

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[25] *Id.*
[26] *Id.*

This number of 55 revision surgeries was and still is increasing consistently as more patients began to experience the often-delayed problems caused by loose tibial components.

121. This number of 55 revisions only accounts for patients that returned to Dr. Lemak for their revision surgery. Relators are aware of several patients that were understandably unsatisfied with Dr. Lemak and the Exactech TKR implant as it failed them within only a few years. Consequently, these patients, some known and surely some unknown, went to another orthopedic surgeon for the revision surgery.

122. Based on Dr. Lemak's data, the approximate failure rate of the Exactech Finned Tibia Tray TKR is at a minimum 25.5% (and estimated to be as high as 35%) over six years. This data comports with the ranges in the only other dataset that assessed the survival rate of the Finned Tray, the Thelu article, of 80.97 ± 9.1% at 36 months and 76.74 ± 12% at 45 months.

123. Dr. Lemak noted the similarities in his patients' outcomes and the Thelu article, but over a shorter time frame. After Carey Christensen, Exactech's Vice President of Sales for the Southeast Region, tried to attack the accuracy of the Thelu article as last-chance effort to keep Dr. Lemak using Exactech products, Dr. Lemak responded:

Dr petty can talk about how these authors publish poor studies. I haven't published anything however my clinical results mirror this study. Was told my dr petty that it was my " poor cementing technique ". Really ? I have just now seen my first smith and nephew gen 2 with aseptic loosening after ten years !!! So guess what my response is to them. These finned trays fail around two years. These are the facts.

I am happy to work with the sports med side and biologics. I will no longer support a company which has failed me and my patients. My reputation as a reconstruction surgeon has been tarnished. Let me know next step. Did my first four biomet joints today. Thanks for supporting my patients and allowing me to implant a prosthesis that has known failures of 25% at 25 months. Mimics my clinical results ..... my " cementing technique ".

124. After being informed by a surgeon who implanted over 200 of Exactech's medical devices that it was a fact "[t]hese finned trays fail around two years" Exactech did not disclose any

of this information to the FDA or anyone else, in violation of regulations specifically designed to prevent such occurrences. *See* 21 C.F.R. § 803.50; 21 C.F.R. § 803.52, 21 C.F.R. § 803.53.

D. Examples of Exactech's Material False Statements Made to Relators Wallace and Farley and to Dr. Lemak, Which Caused False Claims

125. Relator Brooks Wallace became an Exactech sales representative in August 2011. Relator Robert Farley became an Exactech sales representative in 2012. During their respective recruitments, Exactech pitched both Relators Wallace and Farley on the Finned Tibia Tray as the primary Exactech TKR device and the flagship device of the Company. Exactech provided information on how effective, durable, and superior the Finned Tibia Tray was compared to competitor products, even though they knew the Optetrak Finned Tibia Tray was defective and failed at rates far outside industry norms.

126. These statements were made verbally and through Optetrak marketing materials, and specifically the Optetrak Main Brochure, referenced *supra*, wherein Exactech claimed a completely fabricated survival rate of 98.6% at 8.5 years and 99% at 5 years made the Optetrak Finned Tibia Tray an industry leader.[27]

127. Exactech knew these statements and materials were false and misleading because, as addressed *supra*, these false survival rates were outdated, unreliable, and applicable to the pre-2006 Optetrak Finned Tray (Dr. Gradisar's false 98.6% at 8.5 years survival rate) and not applicable to the Optetrak TKR with the Finned Tibia Tray but the Optetrak TKR with the Trapezoid Tray (Dr. Robinson's false 99% at 5 years survival rate). Exactech misled Relators Farley and Wallace by providing clinical evidence related to one device, while instead providing

[27] Optetrak- A Comprehensive Knee System; 712-01-21 Rev. D Optetrak Main Brochure 0410 (2010) available at: https://content.exac.com/wp-content/uploads/sites/3/2016/10/712-01-21_RevD_Optetrak_Main_Brochure.pdf

them a different, woefully defective device for them to sell to unsuspecting physicians, hospitals, patients, and government healthcare programs. By misrepresenting the efficacy of the Finned Tibia Tray in false statements and false promotional materials, the Optetrak Finned Tibia Tray was misbranded and legally prohibited from being introduced into interstate commerce. *See* 21 U.S.C. § 352(a)(1).

128. Key Exactech employees, including Vice President of Sales Bob Purcell, made these false and misleading statements to Relators Wallace and Farley. Mr. Purcell was a long-time Exactech employee and became Vice President of Sales in June 2007[28]—precisely when the deluge of revision surgeries and complaints from sales staff, distributors, and surgeons related to the defective Finned Tray began.

129. These false statements were made to Relators Brooks Wallace and Robert Farley in 2011 and 2012 – years after Exactech had definitive knowledge that there were major flaws with the Exactech Finned Tibia Tray that caused astronomical failure rates. Further, Exactech knew that specific sizes of the Finned Tibia Tray, specifically the size 3 femur, size 2 tibia, which was one of the most common sizes implanted, failed almost invariably. Such representations were also made after numerous surgeons refused to implant the Finned Tibia Tray because of product defects and Exactech provided consulting agreements to multiple surgeons to induce them to continue using Exactech products.

130. At no time during any discussions with Exactech about becoming distributors, the Exactech product line, or the Optetrak Finned Tibia Tray system did Exactech disclose to Relators Wallace and Farley that Exactech had received any information suggesting a potential problem

[28] See Bob Purcell Named Exactech Vice President U.S. Sales (June 12, 2007); https://www.exac.com/bob-purcell-named-exactech-vice-president-u-s-sales/

with the Finned Tibia Tray. There was no disclosure that three years earlier the company conducted multiple investigations demonstrating the device defects and alarming failure rates.

131. Relators Wallace and Farley sought out surgeons and (unknowingly) presented the same false efficacy and survival rate data that Exactech used to recruit Relators Farley and Wallace as distributors. Using false and misleading information supplied by Exactech, Relators Wallace and Farley marketed and sold the defective and misbranded Exactech Optetrak Finned Tibia Tray TKR device to numerous physicians in their Alabama and Northwest Florida territory including: Dr. Joseph Sherrill in Birmingham, AL; Dr. John Young in Birmingham, AL; Dr. James Floyd, in Birmingham, AL; Dr. William Bose in Mobile, AL and Dr. Stephen Blackstock in Gadsden, AL.

132. Relator Brooks Wallace also presented the Exactech Finned Tibia Tray to Dr. David Lemak – a well-respected orthopedic surgeon based in Birmingham, Alabama. Based on false efficacy data and other false sales materials supplied by Exactech falsely touting the superiority of the Optetrak and Finned Tibia Tray, Relator Wallace convinced Dr. Lemak to switch from using Stryker products to the Exactech Optetrak System and the Finned Tibia Tray for all his patients' total knee replacements. These statements, including the false efficacy data in the Optetrak Main Brochure, was known by Exactech to be patently false and misleading in August 2011, at the time it was presented to Dr. Lemak.

133. Exactech directly presented false and misleading efficacy data to Dr. Lemak and withheld critical facts regarding the known failures of the Finned Tibia Tray. Specifically, on October 12, 2011, at the outset of Dr. Lemak beginning to use Exactech products, Relator Wallace and Dr. Lemak went to Exactech headquarters in Gainesville, Florida for a series of meetings. In these meetings, Dr. Lemak and Relator Wallace met with Bob Purcell, Vice President of Sales, and David Petty, founder and CEO, as well as the Exactech Knee Team. Throughout these

meetings, Exactech provided false and misleading efficacy data, propounded the benefits of the Optetrak TKR with Finned Tray, had knowledge that Dr. Lemak would be using the Optetrak Finned Tray, and never disclosed that Exactech had received hundreds of reports of revision surgery and device failure, and had conducted multiple investigations into the Finned Tray failures, which concluded that the Optetrak had several design, manufacturing, and engineering process flaws.

134. Dr. Lemak would have never agreed to implant the Exactech Finned Tibia Tray in his patients, certify that this device was reasonable and necessary, and bill Medicare for defective Exactech Finned Tibia Trays and attendant services, had he known of the Finned Tibia Tray's defects and Exactech's knowledge of such defects.

III. False Claims Caused to Be Submitted by Exactech Related to Patients of Dr. David Lemak

A. Exactech Had Knowledge the Following False Claims Were Submitted to Medicare and Other Government Healthcare Programs

135. From 2011 until 2014, Exactech supplied Relator Wallace with hundreds of Finned Tibia Trays. Each order and billing of an Optetrak Finned Tibia Tray TKR typically happened in the following manner: Relator Wallace would request a certain quantity of Optetrak Finned Tibia Tray TKR devices in varying sizes. Exactech would then ship these devices to Relator Wallace's office in Birmingham. When Dr. Lemak or another surgeon required a device for a patient scheduled for knee replacement, Relator Wallace attended the surgery, carried the full inventory of Optetrak devices, supplied the appropriate size TKR device, and filled out an Exactech form titled "Delivered Goods/Transfer of Inventory."

136. This form provided, among other information, the patient's name and identifying information, including patient age, the hospital that would submit the cumulative billings to the patient's insurer, and the Exactech products and corresponding model number and serial number.

137. Roughly 97.4% of people age 65 and older in the United States are enrolled in the Medicare program.

138. Relators have knowledge that Exactech, as a medical device manufacturer in the United States, is acutely aware of federal health care program involvement in the purchasing and regulation of medical devices. Relators have specific knowledge that Exactech, primarily though Exactech employee Bill Shopoff, negotiated pricing agreements with Health Trust Purchasing Group, the purchasing division of Community Health Systems which owns and operates Grandview Medical Center in Birmingham, Alabama. In this negotiation, the Medicare reimbursement rate for TKR devices is a well-known and primary factor in determining the price of Exactech's implants to Grandview.

139. Relators have knowledge of the Medicaid contracting negotiations conducted to supply Cooper-Green Hospital in Birmingham with Finned Tray devices and that the amount that Exactech negotiated and received for each TKR device sold to Cooper-Green was directly set by Medicaid, the payor of the devices.

140. Further, Relators have knowledge that the accounting department at Exactech, including employee Chris Font, tracked patient payor sources and Exactech has records and knowledge of each device that was paid for by government health care programs, and which government health care program purchased each device.

141. By virtue of Relator Wallace's order forms, Exactech's own contracting negotiations, and its own records, Exactech had knowledge that claims for payment were being submitted to government healthcare programs for its defective medical devices.

142. Yet, Exactech continued to supply an unwitting Relator Wallace and his client, Dr. Lemak, unknowing patients and unsuspecting government health care programs with defective and misbranded medical devices.

B. Specific Examples of False Claims That Exactech Caused to be Submitted

143. Dr. Lemak billed Medicare for 32 knee operations in 2012 under CPT code 27447, the coding for a Primary Knee Reconstruction surgery. Relator Brooks Wallace, as an Exactech distributor and personal sales representative to Dr. Lemak, was the sole supplier of Dr. Lemak's TKR devices and has knowledge that Dr. Lemak exclusively implanted the Optetrak with Finned Tibia Tray during 2012. Further, Relator Wallace personally witnessed Dr. Lemak implant the Finned Tibia Tray for each of these 32 operations. Therefore, in 2012, Dr. Lemak implanted 32 Finned Tibia Tray devices known by Exactech to be defective into the knees of Medicare beneficiaries. In order to sell these 32 devices, Exactech misbranded, materially falsified, and withheld crucial information from Relator Wallace and Dr. Lemak and misled them both. By doing so, Exactech caused the submission of 32 false claims for devices that were not reasonable or medically necessary, in violation of 31 U.S.C. § 3729.

144. By virtue of its false and fraudulent statements and representations detailed herein, Exactech caused Dr. Lemak—via the billing department (specifically, employee Molly Kirk) at Trinity Hospital in Birmingham, Alabama—to expressly falsely certify to CMS Intermediary Cahaba Government Benefit Administrators that each of these 30 claims "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment,

including, but not limited to, the Federal anti-kickback statute...services on this form were medically necessary…I certify that the services listed above were medically indicated and necessary to the health of this patient" as required by CMS Form 1500. These false certifications were made shortly after the surgery and subsequent to Relator Wallace personally providing the signed implant sheet to the billing department, and before Relator Wallace received the end-of-the-month purchase order number corresponding to each surgery.

145. By virtue of its false and fraudulent statements and representations detailed herein, Exactech caused Dr. Lemak—via administrators at Trinity Hospital in Birmingham, Alabama—to falsely certify to CMS Intermediary Cahaba Government Benefit Administrators on the fiscal year 2012 Trinity Hospital Cost Report that these 30 claims "were provided in compliance with laws and regulations regarding the provision of health care services" as required by Form CMS-2552-10. These certifications were false because these claims requested payment for the Optetrak TKR with Finned Tibia Tray—which was not reasonable and necessary in violation of 42 U.S.C. § 1395(a)(1)(A) and misbranded in violation of 21 U.S.C § 352.

146. Similarly, in 2013, Dr. Lemak billed Medicare for 36 knee operations under CPT code 27447. Relator Brooks Wallace, as an Exactech distributor and personal sales representative to Dr. Lemak, was the sole supplier of Dr. Lemak's TKR devices and has knowledge that Dr. Lemak exclusively implanted the Finned Tibia Tray during 2013. Therefore, in 2013, Dr. Lemak implanted 36 Exactech devices into Medicare beneficiaries' knees known by the device manufacturer to be defective. In order to sell these 36 devices, Exactech materially falsified and withheld crucial information from Relator Wallace and Dr. Lemak and misled them both. By doing so, Exactech caused the submission of 36 false claims for devices that were not reasonable

or medically necessary and misbranded, in violation of 31 U.S.C. § 3729. These false certifications were made at the end of the fiscal year when Trinity submitted its yearly cost report.

147. By virtue of its false and fraudulent statements and representations detailed herein, Exactech caused Dr. Lemak—via the billing department (often employee Molly Kirk) at Trinity Hospital in Birmingham, Alabama—to expressly falsely certify to CMS Intermediary Cahaba Government Benefit Administrators that each of these 36 claims "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute...services on this form were medically necessary…I certify that the services listed above were medically indicated and necessary to the health of this patient" as required by CMS Form 1500. These false certifications were made shortly after the surgery and subsequent to Relator Wallace personally providing the signed implant sheet to the billing department, but certainly before Relator Wallace received the end-of-the-month purchase order number corresponding to each surgery.

148. By virtue of its false and fraudulent statements and representations detailed herein, Exactech caused Dr. Lemak—via the administrators at Trinity Hospital in Birmingham, Alabama—to falsely certify to CMS Intermediary Cahaba Government Benefit Administrators on the fiscal year 2013 Trinity Hospital Cost Report that these 36 claims "were provided in compliance with the laws and regulations regarding the provision of health care services" as required by Form CMS-2552-10. These certifications were false because these claims requested payment for the Optetrak TKR with Finned Tibia Tray—which was not reasonable and necessary in violation of 42 U.S.C. § 1395(a)(1)(A) and misbranded in violation of 21 U.S.C § 352. These false certifications were made at the end of the fiscal year when Trinity submitted its cost report.

149. The following are examples of Medicare and Medicaid insured patients who received a defective Exactech Optetrak Finned Tibia Tray, which Exactech knew was misbranded and not reasonable and necessary. Each of these patients' Exactech Optetrak Finned Tibia Tray's failed prematurely causing a Revision Surgery (Adverse Event for MDR reporting purposes). All services and devices attendant to these patients' Primary TKR surgery and Revision TKR surgery represent false claims for payment caused to be submitted by Exactech because such services were caused by Exactech's known defective device, which was misbranded, not reasonable, not necessary, and therefore not reimbursable by Medicare or Medicaid.

- Patient 1, insured by Medicare, was implanted by Dr. Lemak at Trinity Hospital with a defective Exactech Optetrak Finned Tibia Tray TKR on November 25, 2013. The serial number for the defective Finned Tray was 1688415. Exactech received $4,250 for the defective Optetrak TKR device. Exactech's misbranded and known defective device then failed from tibial loosening and Patient 1 required a revision surgery, which was performed by Dr. Lemak at Grandview Medical Center on July 25, 2016.

- Patient 2, insured by Medicare, received a bilateral TKR (knee replacements in both knees) by Dr. Lemak at Trinity Hospital with two defective Exactech Optetrak Finned Tibia Tray TKRs on March 10, 2014. The serial numbers for the respective defective Finned Trays were 2813619 and 2928108. Exactech received $8,500 for the defective Optetrak TKR devices. Both of Exactech's misbranded and known defective devices then failed and Patient 2 required two revision surgeries, performed by Dr. Lemak at Grandview Medical Center on June 20, 2016 (a total revision, requiring all components to be replaced) and July 18, 2016 (a partial revision requiring only the tibia component and poly insert to be replaced). Exactech continued to profit from this Revision, selling the revision devices to Grandview, who then billed Medicare for $7,235.

- Patient 3, insured by Medicare, was implanted by Dr. Lemak at Trinity Hospital with a defective Exactech Optetrak Finned Tibia Tray TKR on May 23, 2012. The serial number for the defective Finned Tray was 1830890. Exactech's misbranded and known defective device then failed from tibial loosening and Patient 3 required a revision surgery, which was performed by Dr. Lemak at Grandview Medical Center on January 9, 2017.

- Patient 4, insured by both Medicare and Medicaid, was implanted by Dr. Lemak at Trinity Hospital with a defective Exactech Optetrak Finned Tibia Tray TKR on July 6, 2012. The serial number for the defective Finned Tray was 2115033. Exactech's

misbranded and known defective device then failed from tibial loosening and Patient 4 required a revision surgery, which was performed by Dr. Lemak at Grandview Medical Center on December 12, 2016.

- Patient 5, insured by Medicare, was implanted by Dr. Lemak at Trinity Hospital with a defective Exactech Optetrak Finned Tibia Tray TKR on June 12, 2013. Exactech's misbranded and known defective device then failed from tibial loosening and Patient 5 required a revision surgery, which was performed by Dr. Lemak at Grandview Medical Center on March 30, 2015.

- Patient 6, insured by Medicare, was implanted by Dr. Lemak at Trinity Hospital with a defective Exactech Optetrak Finned Tibia Tray TKR on December 2, 2013. Exactech's misbranded and known defective device then failed from tibial loosening and Patient 6 required a revision surgery, which was performed by Dr. Lemak at Grandview Medical Center on November 14, 2016.

C. Relator Wallace's Personal Role and Knowledge of Billing Medicare and Medicaid for Dr. Lemak's Patients

150. Dr. Lemak moved his practice and operating room from Trinity Medical Center, located at 800 Montclair Rd. in Birmingham, Alabama to Grandview Medical Center, located at 690 Grandview Parkway, Birmingham, Alabama on October 10, 2015. Therefore, the examples of patients for whom Exactech caused false claims to be submitted, prior to October 10, 2015 received their operations at Trinity, whereas patients after October 10, 2015 received operations at Grandview. However, Relator Wallace has personal knowledge of the billing practices at each hospital and knows that the billing process and personnel at each hospital were the same.

151. For each of the six enumerated patients and the cumulative 32 patients in 2012 and 36 patients in 2013, Relator Wallace personally participated in and has personal knowledge of the billing procedures that took place in order to submit these false claims to Medicare.

152. To submit the false claims for each of these patients, the following events took place: Relator Wallace received the patient information and placed a patient information sticker on an Exactech implant form at the outset of the surgery. He then personally witnessed the surgery take place. Upon completion of the surgery, Relator Wallace then brought the Exactech implant

form to be signed by the "circulator"—a Grandview Medical Center (or Trinity) employee. The circulator's signature authorized that the surgery did in fact occur and that the responsibility for billing for the implants would turn over to the hospital, either Grandview Medical Center or Trinity. Upon receiving the signed implant form, Relator Wallace would make two copies of the form—one for Relator Wallace's records and one to bring to the Grandview Medical Center (or Trinity) Billing Department. Relator Wallace would then fax a copy of the original signed implant form to Exactech. Relator Wallace would then bring the original signed implant form to Tony Diuguid, the Surgery Materials Coordinator at Grandview Medical Center (who was also employed in the same capacity at the Trinity location). Relator Wallace would then personally walk the copy of the signed implant form to the Grandview Medical Center billing department, and hand-deliver it to a billing department employee, often Molly Kirk (who was also employed in the same capacity at the Trinity location), for billing to Medicare, Medicaid, or other insurance providers. The Grandview (or Trinity) Billing Department was then responsible for billing Medicare and Medicaid for the implants.

153. "As a courtesy to [its] patients, [Grandview Medical Center] will bill [the patients'] insurance company, Medicare or Medicaid on [the patients'] behalf."[29] Subsequent to Relator Wallace personally providing the Exactech implant forms to the Grandview Billing Department, the Grandview Billing Department submitted the above referenced false claims for payment to the Medicare and/or Medicaid program.

154. At the end of each month—after Grandview Medical Center had processed its purchase of the Exactech surgical components and submitted claims for these surgeries, and

[29] Grandview Medical Center; Billing & Insurance. Available at: https://www.grandviewhealth.com/hospital-billing-insurance

surgical components, to Medicare and/or Medicaid—Relator Wallace would request Purchase Order Numbers from Tony Diuguid, the Surgery Materials Coordinator. Tony Diuguid would then provide the Purchase Order Numbers to Relator Wallace corresponding to all Exactech component surgeries that had been performed and billed the previous month. Upon receipt of the month's Purchase Order Numbers, Relator Wallace would send these purchase order numbers and corresponding patient information to Brittany Dinatelo, an Exactech employee. Upon submission of these Purchase Order Numbers to Brittany Dinatelo from the preceding month, which showed Grandview Medical Center had purchased the medical devices and billed the patients' insurance provider (Medicare and/or Medicaid for all example patients), Relator Wallace and Gulf Surgical Solutions would receive its commission payment from Exactech for the sale of the devices.

IV. Examples of False Claims Caused to be Submitted to the Medicaid Program

155. The following are examples of patients that received an Exactech Finned Tibia Tray Primary TKR operation by Dr. James Floyd at Cooper Green Mercy Hospital in Birmingham, Alabama. Though the inpatient surgery unit closed in December 2012 due to budgetary issues, Cooper Green Mercy Hospital has long been the sole hospital in the Birmingham Metro Area dedicated to indigent care – providing healthcare for a largely indigent and Medicaid-covered population.

156. Through their knowledge of the pricing negotiations conducted to supply Dr. James Floyd and Cooper Green Mercy Hospital with Exactech Knee Replacements, Relators know that all patients treated by Dr. Floyd at Cooper Green were insured by Medicaid program.

157. At the time the following patients were implanted with Exactech Finned Tibia Tray, Exactech had misrepresented the efficacy of the Exactech Optetrak with Finned Tibia Tray, thus misbranding it in violation of 21 U.S.C. § 352, and had known for over three years that the Finned

Tibia Tray was defective and had a replacement device available, rendering the device not reasonable and necessary in violation of 42 U.S.C. § 1395(a)(1)(A). The following claims are examples of false claims caused to be submitted to the Medicaid and/or Medicare program:

- Patient A.N, a dual-Medicare/Medicaid eligible patient, received a Finned Tibia Tray Right TKR on January 24, 2012. The serial number of the defective and misbranded Finned Tibia Tray is 1532603. The cost of the device to the Medicaid Program was $3,250. Relators have knowledge this price was specially negotiated to allow the Medicaid program to purchase the device—demonstrating Medicaid purchased the device.

- Patient K.P. received a Finned Tibia Tray Right TKR on January 5, 2012. The serial number of the defective and misbranded Finned Tibia Tray is 2176393. The cost of the device to the Medicaid Program was $3,250. Relators have knowledge this price was specially negotiated to allow the Medicaid program to purchase the device—demonstrating Medicaid covered the device.

- Patient G.W. received a size 3F/2T (3 Femur, 2 Tibia) Finned Tibia Tray Right TKR on January 17, 2012. The serial number of the defective and misbranded Finned Tibia Tray is 1310269. The cost of the device to the Medicaid Program was $3,250. Relators have knowledge this price was specially negotiated to allow the Medicaid program to purchase the device—thus demonstrating Medicaid covered the device.

- Patient H.D. received a Finned Tibia Tray Right TKR on February 21, 2012. The serial number of the defective and misbranded Finned Tibia Tray is 2119737. The cost of the device to the Medicaid Program was $3,250. Relators have knowledge this price was specially negotiated to allow the Medicaid program to purchase the device—demonstrating Medicaid covered the device.

158. Relators have knowledge that Exactech regularly contracted with Medicaid-funded hospitals to accommodate Medicaid budget constraints and therefore sold significant Optetrak TKR Finned Tray devices to hospitals that, like Cooper Green Mercy Hospital in Birmingham, submit claims to the joint federal and state-funded Medicaid program.

159. Exactech sold the known-to-be-defective Optetrak TKR with Finned Tibia Tray in several states and caused to be submitted false claims to the Medicaid program because the

Optetrak Finned Tibia Tray was not reasonable or necessary in violation of 42 U.S.C. § 1395(a)(1)(A), misbranded in violation of 21 U.S.C. § 352, and violated the False Claims Act.

V. Examples of False Claims Directly Submitted by Exactech to the Veterans Administration

160. From April 1, 2008 (the date Exactech had definitive knowledge the Finned Tray was defective) to January 1, 2018, Exactech completed 1,580 separate VA contracts.

161. The largest, Contract Number V797P4299A, was a five-year $2,228,280 contract for the delivery of Medical Equipment and Supplies, consisting of hundreds of Primary Knee Replacements and revision knee surgeries. Exactech performed the contract from February 15, 2007, to March 31, 2012. Contract Number V797P299A consists of 249 "Delivery Orders," or separate contract awards. Throughout the five-year contract, each time that a United States Veteran required a knee replacement, a separate Delivery Order would be executed. Each separate Delivery Order for a Total Knee Replacement device requested by the VA, fulfilled by Exactech, and for which Exactech requested payment, was a separate claim for payment. Throughout most of that time period, Exactech knew the Finned Tibia Tray was defective and misbranded, yet continued to supply the Finned Tray to the VA.

162. The Finned Tibia Tray Optetrak TKR was available for sale to the VA through the FSS. For instance, in the 2016 VA FSS, the known-to-be-defective Finned Tibial Tray was available for sale to the VA at a price of $1,118.02.[30] The total cost of an Optetrak TKR device to the VA under this contract, if the Finned Tibia Tray was selected, would be between $4,143.88 and $4,487.33, depending upon which femoral component was used. This VA price could be greater if the patient needed additional hardware.

[30] Tryco Incorporated; Authorized FSS Price List; Contract: V797-P-49-64a; available at: https://www.gsaadvantage.gov/ref_text/V797P4964A/0PGOK2.3AGIBQ_V797P-4964A_V797P4964A02012016.PDF (last visited February 26, 2020)

163. Through individual VA contracts such as Contract V797P4299A and through Federal Supply Schedule listings, Exactech knowingly sold a significant number of defective Finned Tibia Tray Components to VA hospitals.

164. The following are examples of defective Finned Tibia Trays, which represent false claims directly submitted by Exactech to the Veterans Administration:

- Delivery Order V797P4299A-VA571K10199. This Delivery Order is a Firm Fixed Price Federal Contract Award and funded by the Veterans Integrated Service Network 8 (VA-VHA). This award was for a Total Knee Replacement, Category 339112, PSC Category 6515. The Veterans Integrated Service Network 8 paid Exactech Inc. $12,800 for this knee replacement device that Exactech knew to be defective on July 21, 2011.

- Delivery Order V797P4299A-VA573k10218. This Delivery Order is a Firm Fixed Price Federal Contract Award and funded by the Veterans Integrated Service Network 8 (VA-VHA). This award was for a Total Knee Replacement, Category 339112, PSC Category 6515. The Veterans Integrated Service Network 8 paid Exactech Inc. $5,691 for this knee replacement device that Exactech knew to be defective on July 21, 2011.

VI. Exactech's False Statements and Failure to Report Dr. Lemak's Patients Tibial Loosenings and Revision Surgeries, Which Concealed Obligations to Repay Funds to Government Health Care Programs

165. In May 2014, after roughly two and a half years of exclusively using the Optetrak Finned Tibia Tray in over 200 TKR operations, the first of Dr. Lemak's patients required a revision because the defective Finned Tibia Tray came loose.

166. Because it was Relator Wallace's and Dr. Lemak's first time using the more substantial Optetrak Trap Tray Revision system, Relator Wallace requested that Exactech send a corporate representative to oversee the surgery. Exactech sent Anil Matura, a product engineer who worked in Exactech's corporate office in Gainesville, to assist and supervise this revision surgery, which occurred on May 9, 2014. Upon arrival, Mr. Matura saw that the patient undergoing the revision had received the Finned Tibia Tray as the Primary TKR device. Mr.

Matura asked Relator Wallace why Dr. Lemak was using the Finned Tray and not the newer Fit Tibia Tray. Relator Wallace explained that when he joined Exactech as a distributor he was provided the Finned Tibia Tray exclusively and that he, in turn, sold Dr. Lemak on the advantages of the Finned Tibia Tray. Relator Wallace further informed Mr. Matura that, based on Exactech's promotion of the Finned Tibia Tray, he had been exclusively using the Finned Tray for over two years – a fact which Exactech knew by their continued shipment of Finned Tray models.

167. Mr. Matura was shocked to learn that Dr. Lemak had continued to be provided the Finned Tray. Mr. Matura obscurely stated that Exactech is in the process of switching all surgeons to the Fit Tray "because it gives more options" and that Dr. Lemak would immediately and thereafter be provided the Fit Tray.

168. At no point during this 2014 revision and attendant conversations did Mr. Matura inform Relator Wallace that the real reason Exactech was switching surgeons to the Fit Tray was because the Finned Tray was defective and had been determined to cause widespread tibial loosening events and revision surgeries. Nor did Mr. Matura inform Relator Wallace that Exactech had conducted an internal investigation into the Finned Tibia Tray tibial loosening events six years earlier that confirmed those problems. Because of this lack of crucial information, Relator Wallace, at this time, never suspected there was anything wrong with the Finned Tray.

169. As 2014 progressed, however, more of Dr. Lemak's patients returned with pain, instability, and other problems related to tibial loosening of their Optetrak Finned Tibia Trays. Two weeks after Anil Matura attended Dr. Lemak's first Finned Tibia Tray revision, Dr. Lemak contacted Relator Wallace to inform him several more of his patients needed revisions due to early onset Finned Tray tibial loosening.

170. Not only did Relator Wallace report each of these revision surgeries to Exactech and order the Trap Tray implants and other hardware required for each revision surgery, he actively sought answers as to why the Optetrak devices were failing. First, multiple Exactech representatives, including Exactech's Vice President of Sales for the Southeast Region, Cary Christensen, and Exactech engineer Anil Matura, falsely denied that they knew of any other tibial loosening events or problems associated with the Optetrak system or Finned Tibia Tray.

171. Next, when Relator Wallace asked for a more substantive answer than a flat denial of ever previously encountering tibial loosening events, Exactech responded that the cause of the tibial loosening issue was Dr. Lemak's "cement technique"—while continuing to falsely claim that no other surgeon had complained of tibial loosening events. This false answer was equally unsatisfying because not only had Dr. Lemak followed the cement instructions provided by Exactech, but at no point did Exactech offer to review Dr. Lemak's cement technique, provide any further instruction on the "proper cement technique," or otherwise provide any other detail about what specifically was purported to be wrong about Dr. Lemak's cement technique. Moreover, Dr. Lemak was an experienced orthopedic surgeon who had previously never had any problems with his "cement technique" or experienced tibial loosening events and device failures in his patients.

172. Dr. Lemak's frustration with Exactech and the Finned Tibia Tray failures persisted, and he continued to receive unsatisfactory answers from Exactech. Dr. Lemak's frustration is evidenced in an October 9, 2014 email exchange with a relatively low-level Exactech Guided Personalized Surgery (GPS) sales representative, Erik Piorkowski.

173. Mr. Piorkowski reached out to Dr. Lemak, seeking his potential interest in continuing to use the Exactech GPS system and to schedule GPS surgeries, but was met with Dr.

Lemak's ire at the tibial loosening events. Dr. Lemak responded to Mr. Piorkowski's offer to conduct GPS cases by saying:

From: David Lemak <[redacted]
Date: October 9, 2014 at 6:30:37 PM EDT
To: "Piorkowski, Erik" <[redacted]
Subject: Re: ExactechGPS

Tried to call brooks. Have had so many tibia component loosening (2 more last week and one today.) likely going to change prosthesis. Can't deal with revising all these patients in one to two years out.

Sent from my iPhone

174. Because Mr. Piorkowski was a new and relatively low-level Exactech employee, he was apparently unaware of Exactech's knowledge of the tibial loosening issue and its subsequent cover-up (which included never discussing tibial loosening problems over email). Piorkowski forwarded Dr. Lemak's email to a group of Exactech corporate officers and senior employees and requested guidance on how to respond to Dr. Lemak's concerns. The group that Mr. Piorkowski forwarded this email to included: David Petty, CEO; Bill Petty, founder and Chairman of the Board; Gary Miller, Executive Vice President, Research and Development; Bill Shopoff, V.P. of Sales, Laurent Angibaud, Knee Principal Engineer; and Cary Christensen, V.P. of Sales for Southeast region, among others. Because he breached the company's unwritten protocol by taking Dr. Lemak's concerns of tibial loosening at face value and forwarding the email, which could trace knowledge of the problem back to Exactech's corporate officers, Mr. Piorkowski was immediately ostracized within Exactech and bullied into leaving the company within five months of sending this email.

175. Relator Wallace and Dr. Lemak continued to see patients return with tibial loosening problems only one or two years after their primary TKR. Relator Wallace and Dr. Lemak relentlessly raised the issue with Exactech, stating that there was a genuine problem with the Finned Tibia Tray.

176. By December 2014, Dr. Lemak had performed six revisions due to Finned Tray tibial loosening events. These revision surgeries occurred on May 9, 2014 (which an Exactech corporate employee attended); May 12, 2014; July 28, 2014; October 20, 2014; November 11, 2014; and November 17, 2014.

177. Despite six revision surgeries and direct information from an experienced and knowledgeable surgeon that the Optetrak Finned Tray was causing these adverse events, Exactech submitted, at most, only one adverse event report to the FDA. Even if this single adverse event report was related to the revision performed by Dr. Lemak on October 20, 2014, and not another Exactech TKR revision on this same date, this adverse event report contains material false statements and misleading half-truths. Exactech falsely represented to the FDA that the "Event Description" was a "Revision of a total knee arthroplasty due to posterior poly wear. Additionally, there were reports of metallosis from worn titanium."[31] This description is misleading because, assuming this was Dr. Lemak's October 20, 2014 revision, the cause of the revision was tibial loosening caused by the defective Finned Tibia Tray. If, instead, this report was related to another October 20, 2014 adverse event, Exactech reported nothing related to Dr. Lemak's revision surgery of that date, and Exactech reported nothing related to the other five 2014 revision surgeries, in violation of 21 C.F.R. § 803.50 and 21 C.F.R. § 803.53.

178. In December 2014, Exactech corporate officers Bill Shopoff, Vice President of Sales, and Cary Christensen, V.P. of Sales for the Southeast region, traveled to Birmingham to meet with Relator Wallace and Dr. Lemak to discuss the tibial loosening problems.

[31] FDA; MAUDE Adverse Event Report: Exactech, Inc.; Exactech Left Total Knee. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=4365507&pc=JWH

179. During this meeting, Dr. Lemak emphatically described the glaring extent of the tibial loosening events he was encountering in now-routine revision surgeries. Dr. Lemak and Relator Wallace both informed the Exactech corporate officers that during several of the revision surgeries, they discovered that the tibial tray was so loose that Dr. Lemak could simply pull the metal hardware away from the patient's bone using his thumb and index finger. Due to this extreme degree of loosening, Dr. Lemak and Relator Wallace explained to Exactech's representatives that the problems were so pronounced and so unlike anything either of them had witnessed previously, that the loosening must be caused by an issue with the device and not Dr. Lemak's cement technique.

180. At one point, Dr. Lemak exclaimed that, due to the extent of these problems, he did not believe it was possible that that he was the first surgeon to encounter tibial loosening events with the Finned Tibia Tray. To this direct confrontation, Bill Shopoff finally admitted that Exactech had, in fact, seen cases of tibial loosening with two other surgeons – one surgeon in Florida and one surgeon in Oklahoma. This admission only infuriated Dr. Lemak and Relator Wallace further because, for the prior six months, and with revision surgeries mounting, Exactech claimed total ignorance and denied ever receiving reports of any tibial loosening events, and yet after all of those denials, Bill Shopoff finally admitted that Exactech's party line was a lie.

181. After the December 2014 meeting, Exactech attempted to control the damage regarding the situation involving Dr. Lemak. During a follow-up conference call in January 2015, Joseph Pizzurro, Director of Marketing for the Exactech Knee Division, sought to calm Dr. Lemak's concerns by telling him that Dr. Lemak was below the national average for revisions of Exactech Optetrak knee systems. Both Dr. Lemak and Relator Wallace have significant experience in orthopedics, yet had never encountered problems with an orthopedic implant as

severe as with the Optetrak Finned Tibia Tray. Exactech's disclosure that Dr. Lemak was actually below the national average among surgeons for revisions only further highlighted that there were even more extensive tibial loosening problems elsewhere and that Exactech had been lying to Dr. Lemak and Relator Wallace throughout 2014.

182. In follow-up communications with Joseph Pizzurro after the January 2015 conference call, Relator Wallace asked Mr. Pizzurro for further information about Optetrak revisions, including what exactly was the national average for revisions of the Optetrak Finned Tibia Tray TKR. Relator Wallace also relayed Dr. Lemak's demand for meaningful information, specifically the total number of Finned Tibia Tray revision surgeries that had been performed in the United States, or he would no longer use Exactech products. Sensing that this request was far more information than Exactech could share, Pizzurro refused to comply, stating to Relator Wallace: "I won't give any information that would hurt the company."

183. Following the initial revision surgeries in 2014 through early 2015, Dr. Lemak's patients who received Finned Tibia Tray Primary TKRs in the 2011 to May 2014 timeframe continued to return to his clinic, and other Birmingham area orthopedists, with knee pain and instability indicative of tibial loosening problems. Each time a patient returned, Dr. Lemak, accompanied by Relator Wallace, was forced to perform a revision surgery to remove the Finned Tibia Tray and replace it with the Exactech Trap Tray revision system.

184. Relator Wallace estimates that Dr. Lemak performed 55 revision surgeries as of late 2017 – all on patients who were implanted with the Finned Tibia Tray. This figure does not include patients who understandably went to another orthopedic surgeon when their knee replacement – promised to last them 30 years – began failing within less than five years.

185. As the revision surgeries continued week after week, Dr. Lemak grew more enraged and exasperated watching his patients subjected to preventable major knee surgery, because he unknowingly implanted what he was becoming convinced was a defective device. Dr. Lemak's anger and frustration became even more pronounced as he began to suspect that the company who sold the defective device knew it was defective long before Dr. Lemak agreed to use the product and lied to him to induce him to continue to use Exactech products. As the Exactech representative dealing directly with the surgeon on a day-to-day basis, Relator Wallace experienced the full force of Dr. Lemak's anger and frustration.

186. The following situation was indicative of the severity of the loosening problems and Dr. Lemak's growing anger. Relator Wallace was attending one revision surgery at Grandview Hospital in Birmingham when Dr. Lemak was retrieving the loose Finned Tibia Tray from an unconscious patient's knee. Dr. Lemak was able to remove the Tray very easily by simply using his thumb and forefinger to grab the device. Even in other non-Exactech tibial loosening Revision surgeries, a surgeon would need forceps or some other surgical tool to remove a loose tibia tray. Holding the removed Tibia Tray in his hand, Dr. Lemak violently spiked the device onto the floor of the operating room in the direction of Relator Wallace. Throughout this surgery and particularly in this moment, Dr. Lemak was consistently cursing at Relator Wallace and "his company" (Exactech) for causing another one of his patients to undergo an unnecessary revision surgery.

187. On October 13, 2016, Dr. Lemak sent Relator Wallace the following email, with the Subject: Loosening Exactech total knees:

Brooks ,

I know we have assessed this subject many times in the past. I feel that the amount of loosening of the size 2 tibial components on the finned stems which I used for many years is unacceptable and above the normal amount of aseptic loosening. When I last addressed this I was told by Exactech that they haven't seen this as a problem. I fully disagree and continue to see more and more of these that require revisions.

I would like a full list of my revisions due to aseptic loosening. I again request an answer from exactech on the number of failures of this component. I think this needs to be reported.

Regards,

David

Sent from my iPhone

188. Five days later, on October 18, 2016, Dr. Lemak sent Relator Wallace the following email in the same chain:

Brooks,

I have had 3 more tibial stem loosening come into my clinic today. All similar 2-4 years out finned size 2. This is a serious problem that has negatively reflects on me as a surgeon. Makes my name " mud" in the community having to revise so many exactech arthroplasties. That being said , and with the lack of response or admission from exactech , I will be terminating my use of their components. I will of course need to revise the numerous cases that continue to arrive daily.

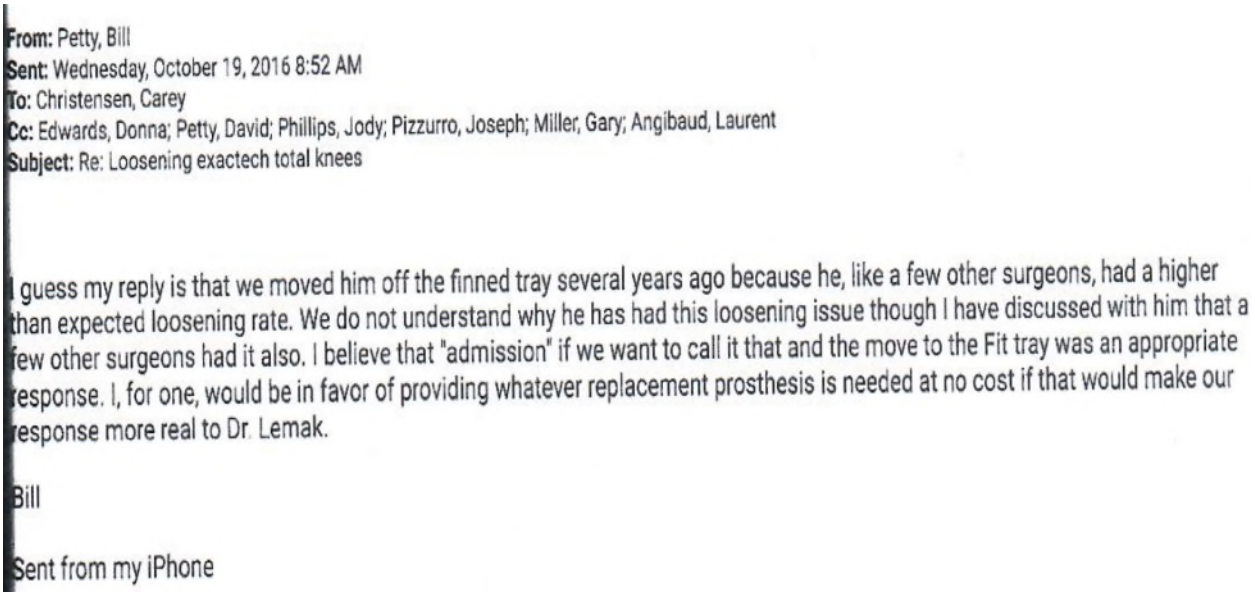
Regards,

David

189. Relator Wallace forwarded this chain of emails to Carey Christensen on October 18, 2016. Carey Christensen, in turn, forwarded the email chain to the highest-level Corporate Officers at Exactech.

190. Bill Petty, Chairman of the Board, Executive Vice President, and Founder of Exactech, responded to Christensen and copied Gary Miller, David Petty, CEO; Jody Phillips,

CFO; Joseph Pizzuro, Director of Marketing for the Exactech Knee Division; Laurent Angibaud, Knee Principal Engineer; and Donna Edwards, Vice President of Legal, on October 19, 2016:



From: Petty, Bill
Sent: Wednesday, October 19, 2016 8:52 AM
To: Christensen, Carey
Cc: Edwards, Donna; Petty, David; Phillips, Jody; Pizzurro, Joseph; Miller, Gary; Angibaud, Laurent
Subject: Re: Loosening exactech total knees

I guess my reply is that we moved him off the finned tray several years ago because he, like a few other surgeons, had a higher than expected loosening rate. We do not understand why he has had this loosening issue though I have discussed with him that a few other surgeons had it also. I believe that "admission" if we want to call it that and the move to the Fit tray was an appropriate response. I, for one, would be in favor of providing whatever replacement prosthesis is needed at no cost if that would make our response more real to Dr. Lemak.

Bill

Sent from my iPhone

191. At no point did Exactech report any of Dr. Lemak's concerns or patient revisions to FDA, in violation of its' regulatory obligations and with specific intent to conceal these problems from the FDA. [32] *See* 21 C.F.R. § 803.53; 21 C.F.R. § 803.50.

VII. Exactech's Offer and Payment of Illegal Remuneration in Violation of the Anti-Kickback Statute

192. As described, *supra*, when a surgeon became frustrated enough with the defective Exactech Optetrak with Finned Tibia tray, Exactech turned to offering the surgeon illegal remuneration in the form of sham "consulting agreements" to continue to purchase Exactech's products. During his tenure with Exactech, Relator Manuel Fuentes witnessed this practice with numerous surgeons throughout the United States. These surgeons experienced tibial-loosening-

[32] MAUDE Database Search: Brand Name: Exactech; Report Date: 10/13/2016 to 12/31/2016. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/results.cfm

related revisions due to the defective Finned Tibia Tray, complained about this problem to Exactech, and were subsequently provided consulting agreements to remain Exactech customers.

193. As alleged herein, Exactech provided the following surgeons with illegal remuneration in the form of consulting agreements to retain their business and secure their silence after their patients suffered a failed knee replacement and required a revision surgery.

Surgeon	**2007 Volume of Finned Tibia Tray Optetrak TKR**	**2008 Volume of Finned Tibia Tray Optetrak TKR**	**Location**
Dr. Raymond Robinson	207	123	Miami, FL
Dr. William Balcom	149	239	Worcester, MA
Dr. Phillip Lewandowski	147	162	Akron, OH
Dr. Scott Dunitz	143	172	Tulsa, OK
Dr. Morton Bertram	93	201	Naples, FL
Dr. Wayne Moody	129	149	Auburn, ME
Dr. David Covall	121	173	Cumming, GA
Dr. Mark Fahey	54	65	Tallahassee, FL
Dr. William Bose	52	84	Mobile, AL
Dr. Ajoy Sinha	57	60	Flushing, NY
Dr. Jay Mabrey	43	72	Dallas, Texas
Dr. Daniel Gallagher	41	59	Marrero, LA
Dr. Richard Boiardo	29	76	Elizabeth, N.J.
Dr. Stephen Davenport		53	Oklahoma City, OK
Dr. James Slater	24	49	Tulsa, OK

Dr. John Aldridge	18	41	Newport News, VA
Dr. James Bates	9	41	San Diego, CA

194. Relators Wallace and Farley personally witnessed Exactech offer and provide illegal remuneration when Exactech was faced with the possibility of losing Dr. Lemak as a customer. Accordingly, Exactech's following illegal conduct is an example of how Exactech provided illegal remuneration to surgeons, including those listed above, to induce them to continue to purchase Exactech devices.

195. In January 2015, when it was clear that Dr. Lemak was very displeased with the mounting device failures and Exactech's deceptive response, Cary Christensen, V.P. of Sales for the Southeast region, approached Dr. Lemak and explained that the Exactech "Sports Medicine Division" (which did not exist) was going to be expanding and that Exactech would appreciate Dr. Lemak becoming a consultant in the new Sports Medicine Division.

196. Specifically, Relator Wallace has knowledge that as of November 13, 2015, Exactech had offered Dr. Lemak a consulting agreement to induce Dr. Lemak's further use of Exactech products, and Exactech employees James Doyle, Eric Knisely, and Thien Doan were actively involved in ensuring Dr. Lemak would be paid for his continued use of Exactech products. Specifically, James (Jim) Doyle, a Principal Engineer and Principal Clinical Consultant with Exactech, coordinated the contact and "interfacing" with Dr. Lemak. Exactech employee Thien Doan was the Exactech employee who superficially "interfaced" with Dr. Lemak – for which he would be paid handsomely.

197. Dr. Lemak had never been offered a consulting agreement by Exactech prior to his threats to stop using and purchasing Exactech's devices, and his consulting agreement was swiftly terminated upon discontinuing purchases of the company's devices.

198. On May 23, 2016, at 10:31 PM, Relator Wallace forwarded Carey Christensen, Exactech's Vice President of Sales for the Southeast Region, a text message from Dr. Lemak, expressing his frustration at the Finned Tray device failures and the lack of meaningful response from Exactech, which read:

> "Not sure about what brooks. It's nothing personal. I have 5 more revisions set up ASAP with the faulty tibial stem. I am about to report these failures to the board. It's above and beyond what's 'acceptable' and when I was 'told it was my technique' it was insulting and unjustified.
>
> These tibial stems are failing at a rate that is above "normal" rate. I have done so many more revisions of exactech tibial stems vs SnN [meaning Smith & Nephew] or Stryker over 10 years plus. I have repeatedly sent requests for explanation and review of cases. Basically laughed at. This is above and beyond 'normal' aseptic loosening.
>
> We have discussed over and over. I have been disregarded by Bill Petty and all others. Time for a change and I will support any patient who has an inquiry regarding their failure."

199. Upon receiving this direct reporting of a pervasive device failure, Exactech was then required to submit a report to the FDA within 5 days of receiving this information to "prevent an unreasonable risk of substantial harm to the public health" or at minimum submit an adverse event report regarding any of the five revision surgeries referenced by Dr. Lemak because—at minimum—the device may have caused or contributed to an adverse event. *See* 21 C.F.R. § 803.53; 21 C.F.R. § 803.50. In violation of these regulations, and with specific intent to conceal these

problems from the FDA, Exactech buried Dr. Lemak's complaints and submitted nothing to the FDA.[33]

200. Instead, Carey Christensen responded by propounding Exactech's policy of dealing with physicians concerned about implanting a defective device by offering illegal remuneration in the form of consulting agreements to induce Dr. Lemak to continue using Exactech products, stating:

> "Suggest you call Dr. Miller. I had a long talk with Thien [Thien Doan, an employee assigned to facilitate consulting payments to Dr. Lemak] and he is ready to come to Birmingham and REALLY [emphasis in original] get David involved with sports side. Its time to get Dr. Miller to Birmingham. Can I forward that text to him?"

The plain meaning of Christensen's email is that it is time to "REALLY" pay Dr. Lemak to continue using Exactech products.

201. On October 10, 2016, Relator Wallace texted Carey Christensen requesting instructions how to fill out Dr. Lemak's timesheet for payment under the sports medicine consulting agreement. In the context of getting such instruction, and illustrating the connection between the tibial loosening events (the cause for Dr. Lemak's threats to discontinue using Exactech products) and the consulting payments, Relator Wallace also let Mr. Christensen know "He [Dr. Lemak] was complaining about tibial loosenings again this am. So wanted to stay on top of that [payment under the consulting contract] for him."

202. The services performed by Dr. Lemak, pursuant to the consulting agreement, further demonstrate that the consulting agreement was a complete sham and simply payment for use of Exactech products. Dr. Lemak met twice with Exactech representatives and talked about

[33] MAUDE Database Search: Brand Name: Exactech; Report Date: 05/23/2016 to 07/23/2016. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/results.cfm

sports medicine generally for a few hours and was paid several hundred dollars per hour for doing so. No products were developed and no meaningful discussions that could lead to product development ever materialized. Dr. Lemak reported to Relator Wallace that the conversations were pointless and that he remained frustrated by Exactech's lack of response to his genuine concern about the tibial loosening events.

203. Exactech paid Dr. Lemak $5,400 in consulting fees in 2016. Based upon the clear connection between Dr. Lemak's decision that it was "time for a change" and that he would no longer be using Exactech's devices and the immediate response that it is time to "REALLY" pay Dr. Lemak to continue using Exactech products, it is apparent that at least one purpose of the $5,400 paid to Dr. Lemak was to induce him to continue to use medical devices that would be, and were paid for, by federal health care programs.

204. The following patients are specific examples of Medicare patients who received Exactech TKR devices at Grandview Hospital in Birmingham, Alabama, subsequent to Exactech's offer and payment of illegal remuneration to Dr. Lemak, and prior to Dr. Lemak's ultimate discontinuation of Exactech products, and therefore represent false claims for payment caused to be presented by Exactech in violation of the False Claims Act and the Anti-Kickback Statute:

- Patient S.C. was a 69-year-old female patient who received an Exactech Total Knee Replacement on June 6, 2016. Specifically, Patient S.C. received 2 line items of Quick Release Pins, at a cost of $145 each, a set of holding pins at a cost of $145, an Exactech Femur, serial number 4358958, at a cost of $1,800, an Exactech Tibia, serial number 3604277 at a cost of $1,445, a cartilage replacement insert at a cost of $550, and a patella at a cost of $250.

- Patient G.C. was a 70-year-old male patient who received an Exactech Total Knee Replacement on June 20, 2016. Specifically, Patient G.C. received 2 line items of Quick Release Pins, at a cost of $145 each, a set of holding pins at a cost of $145, an Exactech Femur, serial number 4328962, at a cost of $1,800, an Exactech Tibia, serial number 4337613, at a cost of $1,445, a cartilage replacement insert at a cost of $550, and a patella at a cost of $250.

- Patient D.O. was a 74-year-old male patient who received an Exactech Total Knee Replacement on June 20, 2016. Specifically, Patient D.O. received 2 line items of Quick Release Pins, at a cost of $145 each, a set of holding pins at a cost of $145, an Exactech Femur, serial number 4311919, at a cost of $1,800, an Exactech Tibia, serial number 4423748, at a cost of $1,445, two cartilage replacement inserts at a cost of $550 each, and a patella at a cost of $250.

- Patient J.S. was a 68-year-old male patient who received an Exactech Total Knee Replacement on June 27, 2016. Specifically, Patient J.S. received 2 line items of Quick Release Pins, at a cost of $145 each, a set of holding pins at a cost of $145, an Exactech Femur, serial number 4062088, at a cost of $1,800, an Exactech Tibia, serial number 3951659, at a cost of $1,445, two cartilage replacement inserts at a cost of $550 each, and a patella at a cost of $250.

- Patient R.B. was a 70-year-old female patient who received an Exactech Total Knee Replacement on June 27, 2016. Specifically, Patient R.B. received 2 line items of Quick Release Pins, at a cost of $145 each, a set of holding pins at a cost of $145, an Exactech Femur, serial number 4335427, at a cost of $1,800, an Exactech Tibia, serial number 4304027, at a cost of $1,445, a cartilage replacement insert at a cost of $550, and a patella at a cost of $250.

- Patient L.C. was a 73-year-old female patient who received an Exactech Total Knee Replacement on July 25, 2016. Specifically, Patient L.C. received 2 line items of Quick Release Pins, serial numbers 4406224 and 4406225 respectively, a set of holding pins, serial numbers 4454126, an Exactech Femur, serial number 4381404, an Exactech Tibia, serial number 4434769, a cartilage replacement insert, serial number 4361429, and a patella, serial number 4387269.

- Patient P.C. was a 78-year-old female patient who received an Exactech Total Knee Replacement on July 25, 2016. Specifically, Patient L.C. received 2 line items of Quick Release Pins, serial numbers 4431107 and 4432081 respectively, a set of holding pins, serial number 4454119, an Exactech Femur, serial number 4389308, an Exactech Tibia, serial number 4434777, a cartilage replacement insert, serial number 4410609, and a patella, serial number 4342750.

- Patient T.W. was a 76-year-old male patient who received an Exactech Total Knee Replacement on August 1, 2016. Specifically, Patient T.W. received 2 line items of Quick Release Pins, at a cost of $150 each, a set of holding pins at a cost of $150, an Exactech Femur, serial number 4416979, at a cost of $3,290.80, an Exactech Tibia, serial number 4441871, at a cost of $1,667.20, a cartilage replacement insert at a cost of $1,070.40, and a patella at a cost of $561.60.

- Patient D.E. was an 83-year-old male patient who received an Exactech Total Knee Replacement on August 8, 2016. Specifically, Patient D.E. received 2 line items of Quick Release Pins, at a cost of $145 each, a set of holding pins at a cost of $145, an Exactech Femur, serial number 4422043, at a cost of $3,290.80, an Exactech

Tibia, serial number 4390841, at a cost of $1,667.20, a cartilage replacement insert at a cost of $1,070.40, and a patella at a cost of $561.60.

- Patient R.V. was a 73-year-old male patient who received an Exactech Total Knee Replacement on September 12, 2016. Specifically, Patient R.V. received 2 line items of Quick Release Pins, at a cost of $145 each, a set of holding pins at a cost of $145, an Exactech Femur, serial number 4422040, at a cost of $1,800, an Exactech Tibia, serial number 3595018, at a cost of $1,445, a cartilage replacement insert at a cost of $550, and a patella at a cost of $250.

- Patient M.R. was a 73-year-old male patient who received an Exactech Total Knee Replacement on his right knee on October 3, 2016. Specifically, Patient M.R. received an Exactech Femur, serial number 4511948 at a cost of $1,800, an Exactech Tibia, serial number 4069354, at a cost of $1,445, a cartilage replacement insert at a cost of $550, and a patella at a cost of $250.

- Patient J.G. was 91-year-old male patient who received an Exactech Total Knee Replacement on October 17, 2016. Specifically, Patient J.G. received 2 line items of Quick Release Pins, at a cost of $145 each, a set of holding pins at a cost of $145, an Exactech Femur, serial number 4465658, at a cost of $1,800, an Exactech Tibia, serial number 4490513, at a cost of $1,445, a cartilage replacement insert at a cost of $550, and a patella at a cost of $250.

205. The Grandview Medical Center billing process for these patients is identical to the Grandview/Trinity billing process, described *supra*. Therefore, Relator Wallace was personally involved in and has knowledge of the process and personnel involved by which each of these false claims—tainted by illegal remuneration—was submitted by the Grandview Billing Department to the Medicare program. To submit each of these false claims, false certifications were made on CMS Form 1500, CMS Form 1450 and CMS Form 2552-10.

COUNT I
Non-Dischargeability Under 11 U.S.C. § 1141(d)(6)(A)
(Incorporating Fraud Under 11 U.S.C. § 523(a)(2)(A))

206. Plaintiffs incorporate the preceding paragraphs of this Complaint.

207. A party asserting non-dischargeability under 11 U.S.C. § 523(a)(2)(A) must prove that:

a. the debtor made the misrepresentations or perpetrated fraud;

b. the debtor knew at the time that the representations were false;
c. the debtor made the misrepresentations with the intention and purpose of deceiving the creditor;
d. the creditor justifiably relied on such misrepresentations; and
e. the creditor sustained loss and damages as a proximate result of the misrepresentations having been made.

Webber v. Giarratano (In re Giarratano), 299 B.R. 328, 334 (Bankr. D. Del. 2003).

208. Defendant engaged in a widespread and systematic fraudulent scheme to continue marketing its defective device long after it became aware, by no later than early 2008, that the device was defective, and therefore was illegal to market and distribute. Specifically, Defendant certified, or caused third parties to certify, that its Optetrak TKR with Finned Tibia Tray was reasonable and necessary for use in primary total knee replacements long after 2008, despite its knowledge of the device's defects, and that under existing laws and regulations it was deemed not reasonable and not necessary. Furthermore, Defendant intentionally supplied false and misleading marketing materials to the general public, and it either concealed reports of adverse effects caused by the device or submitted false and misleading reports of device failure.

209. Doctors and hospitals justifiably relied on the Defendant's misrepresentations regarding the Optetrak TKR with Finned Tibia Tray device, implanted them in patients insured by Medicare, Medicaid, and other programs subsidized by the United States government, and unwittingly submitted fraudulent claims to the United States and state governments for reimbursement of Defendant's defective device.

210. The United States and state governments justifiably relied on Defendant's false and misleading event reports and false claims submitted unwittingly by doctors and hospitals using Defendant's defective device to pay these claims. Therefore, the United States and state governments have suffered damages that were proximately caused by the Defendant's misrepresentations and omissions.

211. Plaintiffs seek a determination that the claims alleged in this Count (and as asserted in litigation pending in the U.S. District Court for the Northern District of Alabama and in proofs of claim that have been or will be filed in this bankruptcy case) and related debts are non-dischargeable pursuant to 11 U.S.C. § 1141(d)(6)(A).

COUNT II
Non-Dischargeability Under 11 U.S.C. § 1141(d)(6)(A)
(Incorporating the Federal False Claims Act,
31 U.S.C. § 3729(a)(1)(A), False Claims Through Third Parties)

212. As specifically alleged in the foregoing paragraphs of this Complaint, Defendant knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A), to wit:

a) Defendant, as an orthopedic device manufacturer in the United States, through its contract negotiations with hospitals and through its own records, had knowledge that government health care programs, including Medicare and Medicaid, would pay and did pay for the Optetrak TKR with Finned Tibia Tray.

b) At the latest, in April 2008, Defendant had knowledge that the Optetrak TKR Finned Tibia Tray was defective beyond any orthopedic device standards, yet sequestered all information related to such defects, including violation of mandatory adverse event reporting requirements under 21 U.S.C. § 360i and 21 C.F.R. § 803.5, 21 C.F.R. § 803.53, 21 C.F.R. § 806.10—rendering the Optetrak TKR with Finned Tibia Tray misbranded and not allowed to be sold in the United States. *See* 21 U.S.C. § 352(t); 21 U.S.C. § 331.

c) Defendant had knowledge of its design, manufacturing and engineering process defects causing the device to be defective, and in violation of cGMP regulations—rendering the Opterak TKR with Finned Tibia Tray "adulterated" and illegally marketed in the United States. 21 U.S.C. § 331.

d) Defendant then made specific false representations regarding the Optetrak TKR with Finned Tibia Tray, including through false and misleading efficacy data contained in device marketing materials—rendering the device misbranded and not allowed to be sold in the United States, in violation of 21 U.S.C. § 331.

e) Based on these false representations, orthopedic surgeons implanted the defective Optetrak TKR with Finned Tibia Tray in patients insured by government funded healthcare programs, including Medicare and Medicaid, and billed these government funded healthcare programs for the defective device. In billing Medicare and Medicaid

for this device, surgeries, revision surgeries caused by device failures and other healthcare costs attendant to the defective device, the orthopedic surgeons, hospitals and other care providers falsely certified that the devices, procedures and care billed was reasonable and necessary and complied with all laws of the Medicare program.

f) Accordingly, Defendant caused the submission of false or fraudulent claims for payment or approval by causing false certifications on forms required for payment of claims under federal healthcare programs, including: Form CMS-1450, Form CMS-1500, Form CMS-2552-10, Form CMS-855I.

213. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed. Defendant's representations were material to the government's decision to pay the device claims and attendant healthcare costs attributable to the defective nature of the device.

214. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

215. As a result of Defendant's violations, the United States has suffered substantial damages in an amount to be determined at trial.

216. Plaintiffs seek a determination that the claims alleged in this Count (and as asserted in litigation pending in the U.S. District Court for the Northern District of Alabama and in proofs of claim that have been or will be filed in this bankruptcy case) and related debts are non-dischargeable pursuant to 11 U.S.C. § 1141(d)(6)(A).

COUNT III
Non-Dischargeability Under 11 U.S.C. § 1141(d)(6)(A)
(Incorporating the Federal False Claims Act,
31 U.S.C. § 3729(a)(1)(A), Direct False Claims)

217. As specifically alleged in the preceding paragraphs of this Complaint, Defendant knowingly presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A), to wit: Defendant knowingly sold the defective Optetrak TKR with Finned Tibia

Tray to the Veterans Administration to be implanted in United States Veterans' knees, with knowledge that the device was not reasonable and necessary and misbranded.

218. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed. Defendant's representations were material to the government's decision to pay the device claims and attendant healthcare costs attributable to the defective nature of the device.

219. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

220. As a result of Defendant's violations, the United States has suffered substantial damages in an amount to be determined at trial.

221. Plaintiffs seek a determination that the claims alleged in this Count (and as asserted in litigation pending in the U.S. District Court for the Northern District of Alabama and in proofs of claim that have been or will be filed in this bankruptcy case) and related debts are non-dischargeable pursuant to 11 U.S.C. § 1141(d)(6)(A).

COUNT IV
Non-Dischargeability Under 11 U.S.C. § 1141(d)(6)(A)
(Incorporating the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B))

222. As specifically alleged in the preceding paragraphs of this Complaint, Defendant knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claims for payment in violation of 31 U.S.C. § 3729 (a)(1)(B), to wit:

> (a) Defendant made and disseminated false statements, marketing materials and device efficacy studies to induce physicians and hospitals to purchase its defective product;
>
> (b)These false records and statements falsely represented the most critical information related to the defective Optetrak TKR with Finned Tibia Tray—the survival rate data—and such false statements were material to inducing surgeons to purchase and implant the

Optetrak Finned Tray and falsely certify that the Optetrak TKR with Finned Tray was reasonable and necessary and not misbranded.

223. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed. Defendant's representations were material to the government's decision to pay the false claims.

224. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

225. As a result of Defendant's violations, the United States has suffered substantial damages in an amount to be determined at trial.

226. Plaintiffs seek a determination that the claims alleged in this Count (and as asserted in litigation pending in the U.S. District Court for the Northern District of Alabama and in proofs of claim that have been or will be filed in this bankruptcy case) and related debts are non-dischargeable pursuant to 11 U.S.C. § 1141(d)(6)(A).

COUNT V
Non-Dischargeability Under 11 U.S.C. § 1141(d)(6)(A)
(Incorporating the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(G))

227. As specifically alleged in the preceding paragraphs of this Complaint, Defendant knowingly made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, and/or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government in violation of 31 U.S.C. § 3729 (a)(1)(G), to wit:

(a) Defendant made numerous false records and statements to surgeons, including Dr. David Lemak, regarding the long history of failures of the defective Optetrak TKR with Finned Tibial Tray when these surgeons sought answers regarding their patients' device failures;

(b) Through these false statements, Exactech prohibited these surgeons and hospitals from learning that they submitted false claims for payment and therefore had an obligation to repay Medicare and/or Medicaid for these false claims;

(c) Defendant's false statements prohibited the repayment for false claims and therefore material to these obligations to repay Medicare and/or Medicaid.

228. Because of these false or fraudulent statements, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

229. As a result of Defendant's violations, the United States has suffered substantial damages in an amount to be determined at trial.

230. Plaintiffs seek a determination that the claims alleged in this Count (and as asserted in litigation pending in the U.S. District Court for the Northern District of Alabama and in proofs of claim that have been or will be filed in this bankruptcy case) and related debts are non-dischargeable pursuant to 11 U.S.C. § 1141(d)(6)(A).

COUNT VI
Non-Dischargeability Under 11 U.S.C. § 1141(d)(6)(A)
(Incorporating the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b))

231. As specifically alleged in the preceding paragraphs of this Complaint, Defendant knowingly presented or caused to be presented numerous false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729 (a)(1)(A).

232. By virtue of the kickbacks (in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)), misrepresentations, and submissions of non-reimbursable claims on a corporate-wide basis described above, including those specific claims tainted by illegal remuneration identified herein, Defendant knowingly presented or caused to be presented false or fraudulent

claims for the improper payment or approval on behalf of federal health care program beneficiaries.

233. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed. Defendant's representations were material to the government's decision to pay the claims.

234. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

235. As a result of Defendant's violations, the United States has suffered substantial damages in an amount to be determined at trial.

236. Plaintiffs seek a determination that the claims alleged in this Count (and as asserted in litigation pending in the U.S. District Court for the Northern District of Alabama and in proofs of claim that have been or will be filed in this bankruptcy case) and related debts are non-dischargeable pursuant to 11 U.S.C. § 1141(d)(6)(A).

PRAYER FOR RELIEF

WHEREFORE, the United States, by and through relators Brooks Wallace, Robert Farley, and Manuel Fuentes, respectfully request that this Honorable Court enter judgment:

a. finding Exactech, Inc. liable for fraud and for violations of the federal and relevant state False Claims Acts and the Anti-Kickback Statute,

b. awarding damages in an amount to be determined at trial,

c. determining that that these claims are non-dischargeable pursuant to 11 U.S.C. § 1141(d)(6)(A), and

d. providing such other relief as may be just.

Respectfully submitted,

Dated: February 3, 2025

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